AAPH Resolution and White Paper
The Case for Harm Reduction
for Control of Tobacco-related Illness and Death
Prepared by
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On behalf of the Tobacco Control Task Force, AAPH
As amended and passed by the AAPH General Membership
October 26, 2008

Abstract

"Tobacco Harm Reduction" is taken to mean encouraging and enabling smokers to reduce their risk of tobacco-related illness and death by switching to less hazardous smokeless tobacco products.

In practical terms, enhancement of current policies based on the premise that all tobacco products are equally risky will yield only small and barely measurable reductions in tobacco-related illness and death. Addition of a harm reduction component, however, could yield a 50% to 80% reduction in tobacco-related illness and death over the first ten years, and a likely reduction of up to 90% within 20 years. These projections are based on the expectation that a significant number of smokers will continue to smoke and the knowledge that risk of death from lung cancer continues for decades after the smoker has stopped smoking.

The literature review and bibliographic references that stand behind these projections are to be found in this AAPH White Paper.

Executive Summary

"Harm Reduction" in the context of this executive summary is taken to mean encouraging and enabling smokers to reduce their risk of tobacco-related illness and death by switching to less hazardous tobacco products. This switch could be short-term or long-term, partial or full, with the understanding that every time an alternative tobacco product is used in place of a cigarette, risk of tobacco-related illness and death is reduced.

A simplified explanation of the risks of different tobacco products can be provided using a scale from zero to 100, with a score of 100 representing the average loss of 8 years of life due to cigarette smoking and a score of 0.001 representing the level of risk acceptable to the American public for other consumer products. This represents a five order of magnitude (one million times) difference in risk of death comparing cigarettes to foods and over-the-counter medications.

More than 90% smoking-related deaths are due to lung cancer, other pulmonary diseases, and cardiovascular diseases among smokers; and deaths in non-smokers from environmental tobacco smoke. Switching to smokeless tobacco would eliminate these risks. There is no disease for which the risk from smokeless tobacco is greater than the risk for smoking. Therefore, the theoretical maximum risk for a smokeless tobacco product would be about 10 (one order of magnitude less risk than cigarettes).

The problem with cigarettes appears to be the process of combustion itself, with direct inhalation of concentrated products of combustion. Some experts believe that such smoking of any plant material (even dried cabbage or lettuce) would yield high rates of cardiac and pulmonary disease and cancer, even without the carcinogens present in tobacco.

Case-control studies show that the highest risk smokeless tobacco product, powdered dry snuff, confers a risk rating of about 2. The best available data suggests that the lowest risk smokeless tobacco product (low nitrosamine snus) carries a theoretical risk rating of about 0.3. Thus, while reducing the risk of tobacco related death by more than 98% (two orders of magnitude less risk) smokeless tobacco products are still 300 to 2,000 times more hazardous (two to three orders of magnitude more risk) than foods and over-the-counter medications.

Current tobacco control policies are based on the premise that all tobacco products are equally risky, and that smokers should quit or face death from tobacco-related illness. This policy ignores what we know about the relative risk of smokeless tobacco products, and ignores what we know about the strength of the nicotine addiction.

In practical terms, enhancement of current policies will yield only small and barely measurable reductions in tobacco-related illness and death. Addition of a harm reduction component, however, could yield a 50% to 80% reduction in tobacco-related illness and death over the first ten years, and a likely reduction of up to 90% within 20 years. These projections are based on the expectation that a significant number of smokers will continue to smoke and the knowledge that risk of death from lung cancer continues for decades after the smoker has stopped smoking.

Many who oppose tobacco harm reduction mistakenly believe that switching from cigarettes to smokeless tobacco will increase the risk of oral (mouth and throat) cancer. This is simply not true. There is no illness and no form of cancer for which any form of smokeless tobacco carries a risk higher than the risk from cigarette smoking. Both smoking and use of smokeless tobacco cause white patches in the mouth known as leukoplakia. Smoking-related leukoplakia account for 75% of oral cancer in the U.S.A. Smokeless tobacco related leukoplakias rarely progress to cancer.
Another common objection to tobacco harm reduction is based on the expectation that encouraging smokers to switch to smokeless tobacco will increase the numbers of teens initiating tobacco use and decrease the numbers of smokers who quit. Experience in Sweden shows that it is feasible to get smokers to switch to snus (a low risk form of smokeless tobacco consisting of moist snuff usually sold in miniature tea-bag-like pouches to be placed between the upper lip and gum) without increasing the number of children and youth initiating tobacco use and without decreasing the number of smokers who quit each year.

Even if a harm reduction approach doubles the number of people using tobacco products in the United States, the order-of-magnitude differences in risk of illness and death comparing smoking to smokeless tobacco products would still result in the same 50% to 80% reduction in tobacco-related illness and death over the first ten years, and a likely reduction of up to 90% within 20 years.

Thus, it is our (The American Association of Public Health Physicians) perception that the current base of tobacco-related science is more than sufficient to support adding harm reduction as a component of programming intended to reduce tobacco-related illness and death.

While some have proposed limiting harm reduction to medicinal nicotine products, such a limitation would likely place the reduced risk products out of reach of rebellious teens, socially disadvantaged minorities, gays, and other high risk groups. We are therefore recommending that the approach to harm reduction be based on tobacco products sold in the same retail outlets as cigarettes, and at comparable prices.

All this considered, children and youth should be advised never to initiate tobacco use, and current tobacco users should be encouraged to quit. For smokers unable or unwilling to quit (that is, they are unable or unwilling to overcome their addiction to nicotine), encouraging them to switch to the lowest risk ST products would be an effective way for them to reduce their risk of tobacco-related illness and death.

The literature review and bibliographic references that stand behind this Executive Summary are to be found in this AAPHP White Paper.

This resolution and white paper were approved by the American Association of Public Health physicians at their general membership meeting in San Diego, October 26, 2008.
Resolution on Tobacco Harm Reduction

Whereas there is substantial scientific evidence that selected smokeless tobacco (ST) products can satisfy the nicotine addiction of invertebrate smokers while eliminating most, if not all, risk of pulmonary and cardiovascular complications of smoking while reducing the risk of cancer by more than 95% and

Whereas transitioning smokers to selected ST products will eliminate environmental tobacco smoke and fire-related hazards and

Whereas current "abstain, quit, or die" tobacco control policies in the United States may have reached their maximum possible public health benefit because of the large number of cigarette smokers either unwilling or unable to discontinue their addiction to nicotine, and

Whereas there is evidence that harm reduction works and can be accomplished in a way that will not increase initiation or impede smoking cessation and

Whereas health-related agencies and organizations, both within the United States and Abroad have already gone on record endorsing Harm Reduction as an approach to further reducing tobacco related illness and death, and

Whereas current federal policy requires tobacco product labeling that leaves the incorrect impression that all tobacco product present equal risk and

Whereas certain tax policies put ST products at a competitive disadvantage, compared to cigarettes, and

Whereas harm reduction approaches to reducing tobacco-related illness and death promise to be more politically and financially viable than alternative approaches because harm reduction approaches can secure the support of many tobacco-industry-related stakeholders.

Be it Therefore Resolved that the American Association of Public Health Physicians go on record as favoring Harm Reduction as a component of public health efforts to reduce tobacco-related illness and death and

Be it further Resolved that such efforts shall encourage the following approaches:

1. Product labeling to inform consumers of the relative risk profiles of the various classes of tobacco products.
2. Governmental and health-organization sponsored health education to educate consumers to the risk profiles of the various classes of tobacco products
3. Revision of taxation schemes at federal, state, and local levels to reflect risk profiles and costs to society of the various classes of tobacco products
4. Regulation of the manufacturing and marketing of the various classes of tobacco products reflective of their respective risk profiles and costs to society.

Be it further Resolved that funds be established through taxation of tobacco products to facilitate government-sponsored (as opposed to tobacco company sponsored) research and program evaluation to refine our understanding of the relative risk profiles of the various classes of tobacco products, market trends, and the impact of governmental policy and programming on tobacco product consumption.

Whereas #1 – Evidence of Lower Risk

Health Risks of Cigarette Smoking

As background for this literature review, the following summary data is provided from the Centers for Disease Control (CDC) web site. [1, 2]

"Cigarette smoking is the leading cause of preventable death in the United States and produces substantial health-related economic costs to society." [1]

About 438,000 U.S. deaths are attributable each year to cigarette smoking. [2] Of these, about 38,000 are due lung cancer or ischemic heart disease due to exposure to environmental tobacco smoke. [2]

Table 1.
Annual Smoking-Attributable Deaths in the United States among 45 Million Smokers

<table>
<thead>
<tr>
<th>Cause of Death</th>
<th>Range of RR</th>
<th>Estimated Numbers of Deaths Per Year in the United States</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cancer</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mouth and throat</td>
<td>5-11</td>
<td>4,868</td>
</tr>
<tr>
<td>Pancreas</td>
<td>2.3</td>
<td>6,509</td>
</tr>
<tr>
<td>Lung</td>
<td>13-23</td>
<td>123,836</td>
</tr>
<tr>
<td>Other</td>
<td></td>
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<td>Respiratory Disorders</td>
<td></td>
<td>101,454</td>
</tr>
<tr>
<td>All Deaths Among Smokers</td>
<td></td>
<td>397,962*</td>
</tr>
<tr>
<td>Environmental Tobacco Smoke</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lung cancer</td>
<td></td>
<td>3,000</td>
</tr>
<tr>
<td>Cardiovascular</td>
<td></td>
<td>35,000</td>
</tr>
<tr>
<td>All Environmental Tobacco Smoke</td>
<td></td>
<td>38,000*</td>
</tr>
<tr>
<td>All</td>
<td></td>
<td>435,962*</td>
</tr>
</tbody>
</table>

1 RR – Relative Risk, the ratio of risk comparing users to non-users; an RR of 1 means no increased Risk, 1.2 means a 20% increase, 2.0 means double the risk, etc. Range reflects differences from different case-control studies
3 CDC, http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5405a1.htm
4 Does not include small numbers of deaths from a variety of other causes

(note: Estimated numbers of deaths derived by CDC by a complex software package using data from research studies, national surveys, and death records)
ST Use- Cardiiovacular Disease

Over the past 15 years, ten epidemiologic studies have examined the risk of cardiovascular diseases among ST users. Eight of the studies found that ST users had no increased risk for heart attacks or strokes [3-10]. The other two reported modestly positive associations, with ST users having relative risks compared to non-users (RRs) of 1.2 and 1.4 [11,12], which are lower than those of smokers.

In 2003, Asplund completed a comprehensive review of the cardiovascular effects of ST use [65]. He concluded that, in distinct contrast to smokers, ST users do not exhibit any significant differences from nonusers of tobacco with regard to the following measures of cardiovascular health: heart rate, blood pressure, cardiac output and maximal working capacity, levels of hemoglobin and hematocrit, leukocytes, antioxidant vitamins, fibrinogen, components of the fibrinolytic system, C-reactive protein and thromboxane A2 production. In addition, ST users did not show important smoking-associated vascular changes, including increased thickness of blood vessels and atherosclerotic plaque development. In summary, most of the medical and epidemiologic evidence documents that ST users do not have elevated risks for cardiovascular diseases.

ST Use- Pulmonary Disease

According to the 2007 statement on harm reduction by the Royal College of Physicians in London, "ST products have little or no effect on the risk of chronic obstructive pulmonary disease or lung cancer." [14]

In February of 2008, a European Commission released a report on the health effects of ST products including the following statements:

"Respiratory diseases, predominantly lung cancer, COPD and pneumonia, account for 46% of the deaths caused by cigarette smoking in the EU (The ASPECT Consortium 2004). There is no consistent evidence that any ST products cause any of these major respiratory diseases. Complete substitution of ST products for tobacco smoking would thus ultimately prevent nearly all deaths from respiratory disease currently caused by smoking, which in total represent nearly half of all deaths caused by smoking." [15]

In a 2007 paper on snus, Foulks and Kozlowski concluded: "Importantly, for two of the most prevalent smoking-caused diseases (lung cancer and chronic obstructive pulmonary disease), snus poses no risk." [16]

Oral leukoplasia

Oral leukoplasia is a term used frequently in discussions about ST use. In 1978 the World Health Organization defined oral leukoplasia as a "white patch or plaque that cannot be characterized clinically or pathologically as any other disease." [17] Later this definition was recognized as overly broad; in 1984 it was revised to distinguish leukoplasias associated with ST use from those associated with smoking (18). The distinctions were based on prevalence, the location in the mouth, the proportion showing microscopic features of dysplasia, and the rate of malignant transformation (18,19).

Oral leukoplasia is a rare condition, occurring in less than 1% of the general population. Smoking-related leukoplasias occur primarily in long-time smokers 40 to 60 years old (20,21), and they most commonly involve the undersurface of the tongue and soft palate, locations accounting for 75% of oral cancer in the U.S. (21,22)

Leukoplasias are seen in up to 60% of ST users (23,24), within 6 months to 3 years of starting ST use (25,26). They primarily occur at the site of ST use (i.e. mucosa of the gingival and lip) and are largely a result of local irritation (25,27). The frequency of appearance depends on the type of ST that is used. Moist snuff is more strongly associated with leukoplasia than chewing tobacco, which is attributed to high ph among the former (26). However, leukoplasia is less frequently seen in users of pre-portioned pouches than in those using loose forms of moist snuff (28).

There are distinct differences in the prevalence of dysplasia in leukoplasias associated with ST and smoking. Dysplasia is seen infrequently in ST leukoplasias (less than 3%) (29-32). Furthermore, even when dysplasia is present in ST leukoplasia, it usually is found in earlier stages than in leukoplasias due to smoking (33,34), where it is seen in about 20% of cases (35).

ST leukoplasias only rarely progress to cancer. For example, one prospective study found no case of cancer in 1,550 ST users with leukoplasia who were followed for 10 years (36), and a second study reported no case of oral cancer among 500 regular ST users followed for six years (37). A retrospective study of 200,000 male snuff users in Sweden found only one case of oral cancer per year, an extremely low frequency (38). In a more recent study, a group of 1,115 snus users in Sweden who presented with leukoplasia in 1973-74 were followed for 27-29 years. The study documented that the lesions had completely disappeared in 62 persons who had quit snus permanently. Cancer record linkages revealed three cases of oral cancer, resulting in a standardized incidence ratio of 2.3 (95% CI = 0.5-6.7) (39).

Leukoplasias in smokers have a higher rate of malignant transformation. In 1984 a follow-up study reported that 17% of smoking leukoplasias transformed into a cancer over seven years (40).

In summary, leukoplasia occurs commonly in ST users, but it primarily represents irritation and only very rarely progresses to oral cancer. In 2008 a systematic review of the epidemiologic evidence came to the following conclusion:

"Thirty-three epidemiological studies consistently show a strong dose-related effect of current snuff on oral mucosal lesion prevalence. In Scandinavia, users have a near 100% prevalence of a characteristic "snuff-induced lesion", but prevalence of the varied lesions reported in the USA is lower. Associations with chewing tobacco are weaker. The lack of clear association with former use suggests reversibility following cessation, consistent with experimental studies showing rapid lesion regression on quitting." [41]

ST Use- Cancer

Oral Cancer: ST use has been associated with cancer – most specifically oral cancer – for many decades. It is widely perceived – both by laypersons and medical professionals – that the association is strong and applies to all ST products. However, epidemiologic studies dating back to the 1950s provide convincing evidence that most ST products increase oral cancer risks only minimally.

Rodu and Cole reviewed 21 epidemiologic studies published from 1957 to 1998 [42]. Unlike previous reviewers, these authors derived relative risk (RR) estimates for cancers of the mouth and
associated upper respiratory sites related to use of chewing tobacco, moist snuff, dry snuff and a fourth category in which the type of ST was unclear or undetermined (ST unspecified). This study found that use of chewing tobacco and moist snuff were associated with only minimally elevated risks, while use of dry snuff conferred higher risks.

Chewing tobacco has been studied at least once in each of four decades from the 1960s to the 1990s. The data clearly show that chewing tobacco use is associated with only slightly elevated cancer risks; RRs for all anatomic sites are under 2 with confidence intervals including 1 (i.e. no perceptible increase in risk). The first study evaluating the risk of chewing tobacco appeared in 1962 [43]. There were two studies in 1977 [44,45], two in 1988 [46,47], and four studies from 1993 to 1998 [48-51].

As with chewing tobacco, summary RRs are only slightly elevated for moist snuff, with three RRs at or below 1 and the highest RR at 1.2. RRs for moist snuff were reported first in 1977 [44]. Another study appeared in 1988 [47], and five additional studies were published from 1993 to 1998, as this ST type came under intense scrutiny [48-52].

Two of the seven studies on moist snuff were Swedish, both appearing in 1998 [51,52]. These studies have received considerable attention among tobacco researchers, particularly in Europe, because they are viewed as showing no oral cancer risk for Swedish products. They formed the basis for the Swedish government’s decision in 1999 to recommend that the European Union (EU) oral cancer warning labels be removed from ST products. An EU directive in 2001 accomplished that objective and specified a new warning, “This tobacco product can damage your health and is addictive” [53]. Notably, the other five studies contributing to the summary RRs for moist snuff were American, and they reported RRs very similar to those of the Swedish studies.

Summary RRs for dry snuff use are higher, ranging from 4 to 13, although the confidence intervals for these estimates are wide. The first study appeared in 1962 [43], followed by studies in 1981 [54], 1988 [46], and 1994 [49], spanning a period of 32 years.

Eight studies provided RRs for ST-unspecified, five of which appeared between 1957 and 1969 [55-59]. Additional studies appeared in 1992 [60], 1993 [48] and 1998 [61]. RRs for ST-unspecified range from 1.3 to 4.8, and most are statistically significant. For all sites, the summary RR is 1.9 (CI=1.5-2.3), which is intermediate between the low risks reported for chewing tobacco (1.2, 1.0-1.4) or moist snuff (1.0, 0.8-1.2) and the higher risk for dry snuff (5.9, 1.7-20). The intermediate risks for this ST category probably reflect the use of either the lower- or higher-risk products among different groups within the studies.

Prior to the 2002 analysis by Rodu and Cole, the distinctive risk profiles of moist snuff and chewing tobacco on one hand, and dry snuff on the other, had gone unnoticed. In fact, the low oral cancer risk associated with chewing tobacco had been discussed briefly in only one article [62]. No distinction in risks had been made previously between dry snuff and moist snuff, even though these products are considerably different with regard to tobacco content and processing, as noted earlier.

The distinction between the higher risk profile of American dry snuff and the minimal risk conferred by chewing tobacco and moist snuff continues to be ignored in reports from governmental and other organizations. In 2007 the International Agency for Research on Cancer issued IARC Monograph 89 on ST products [63]. Although the publication distinguished between chewing tobacco, moist snuff and dry snuff in the section on ST use, no such distinction was made in the

section on health effects. Similarly, in 2008 the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) from the European Union issued a report on the health effects of ST products [64]. Differences in risk among American products were minimized, even after a communication from the present author (BR) providing the scientific basis for the distinction. On the other hand, in 2007 the Royal College of Physicians issued a report on tobacco harm reduction, which contained a section on the health risks of ST use [44]. That report clearly discussed oral cancer risks separately for American moist snuff, chewing tobacco and dry snuff, and it further stated that the 1981 Winn study [54], showing the highest risks for oral cancer, was based exclusively on women in the Southeast U.S. who used powdered dry snuff. It is difficult to understand why the IARC and SCENIHR reports failed to make a similar distinction, since the details of the Winn study were disclosed by Winn herself in an IARC publication [65] and in another scientific publication [66].

The majority of epidemiologic studies regarding ST use and oral cancer have limitations, many of which are typical for case-control studies, and some important for understanding unique oral cancer risks. Most of them did not control for confounding by two strong determinants of oral cancer, cigarette smoking and alcohol use. Positive confounding by smoking would occur if ST users smoke more than do nonusers of ST. This would result in artificially high risk estimates for oral cancer among ST users. On the other hand, negative confounding is plausible and would occur if smoking rates are lower among ST users than among nonusers of ST. This would result in artificially low risks for oral cancer among ST users.

Only three studies [51,52,54] controlled for alcohol use, where only positive confounding is likely. Thus, control for alcohol consumption in all studies probably would have reduced somewhat many of the estimates of mouth cancer risk associated with ST use.

However, even with these limitations, the results of these studies are reasonably consistent with regard to mouth cancer risks from long-term use of moist snuff and chewing tobacco. In their review Rodu and Cole concluded that “the abundance of data now available indicates that commonly used ST products increase the risk of oral and upper respiratory tract cancers only minimally.” [42]

Since the 2002 review five epidemiologic studies, two from Sweden and three from the U.S., have been published [67-71]. In all of these studies ST use was not associated with a significant increase in mouth cancer risk. In 2004 a group of epidemiologists concluded that the evidence linking ST use and oral cancer was “not decisive” [72]. These investigators commented that many claims in the media “overemphasize the risk of oral cavity cancer [from ST use], reaching beyond the scientific data.”

In 2007 a meta-analysis concluded that “ST, as used in America or Europe, carries at most a minor increased risk of oral cancer.” [73]

Pancreas cancer. Since 2004 four epidemiologic studies have evaluated the risk of pancreas cancer among ST users; two were based in the U.S., one in Norway and one in Sweden. An American study published in 2004 revealed that ever ST users had a RR of 1.4 (95% CI = 0.5 - 3.6) for pancreas cancer, compared with non-users of tobacco [74], and the RR was 1.1 (95% CI = 0.4 - 3.1) among exclusive ST users. The study did not control for diabetes or family history of pancreas cancer, which had been found in a previous report to be significant risk factors for the disease in this cohort [72].
In 2005 a study based in Norway found that ST users had a RR of 1.7 (95% CI: 1.1 - 2.5) [76], compared with nonusers of tobacco. However, this study was strongly criticized on a number of technical issues [77]. First, the investigators created a mixed referent group for the SLT analysis by combining never and occasional users (the designation of exposure groups, and especially of the referent group, greatly affects risk estimates in a study as small as this). They failed to provide risk estimates using the four customary SLT exposure categories that they described in their methods section: never users (referent group), regular current, occasional current, and regular former users. Second, they did not control for alcohol use. This was a critical error, as alcohol consumption was reported as the strongest risk factor for pancreas cancer in the earlier report of this cohort, with odds ratios up to 11 [78]. Finally, the study authors used an unusual procedure to adjust for the effects of smoking, which may have affected the risk estimates for ST users.

In 2007 a Swedish study found that Swedish construction workers who currently used ST had a RR of 2.1 (95% CI: 1.2 - 3.6) [71], compared with nonusers of tobacco. This study is one of a series produced by investigators at the Karolinska Institute.

In 2007 a case-control study involving 800 patients with pancreas cancer and 800 controls found that there was no association between ever-use of chewing tobacco or snuff and pancreatic cancer [79]. The adjusted odds ratio among chewing tobacco users was 0.6 (95% CI: 0.6 - 1.4), and the adjusted odds ratio for snuff users was 0.5 (95% CI: 0.1 - 1.5), when compared with never-users of tobacco. The results were adjusted age, sex, race/ethnicity, cigarette smoking, history of diabetes, alcohol consumption, educational level, state of residency, and marital status. This study found that the odds ratio among ever smokers was 1.6 (95% CI: 1.2 - 1.9), and a dose-response effect based on pack-years was evident.

Comparison of the health risks of ST use with those of smoking

According to the most recent data from CDC, [1,2] only 34% of smoking-related deaths are due to cancer. Since the data in the literature reviewed above suggests that the only substantial health hazard of ST is related to cancer at sites other than the lung, substituting ST for cigarettes would reduce the death toll from tobacco products from 438,000 per year to less than 34,700. The more detailed studies, presented in the literature review in this report suggest that, with a focus on the lowest risk ST products, this death toll could be reduced to less than 2% of the overall cancer risk of smoking - a death toll of less than 3,000 per year.

One major issue related to the extreme health hazard posed by cigarettes has to do with the means by which the hazardous chemical substances are transmitted to the human body, and the related issue of other chemicals produced in the combustion process. Burning tobacco generates carbon monoxide, which, in conjunction with the nicotine, substantially stresses the heart and cardiovascular system. The combustion process also produces gasses and small particles that are then directly transmitted to the smaller bronchi and the alveoli of the lung - possibly the most delicate and vulnerable tissues in the human body. Some experts in this field feel that smoking of any biomass, even without the nicotine and tar of cigarette smoke, would produce similar pulmonary, cardiac, and even cancer-related rates of illness and death [80].

The established health risks associated with ST use are vastly lower than those of smoking. In the past 25 years, numerous peer-reviewed scientific and medical publications have acknowledged the differential risks between the two tobacco products.
estimated that, compared with smoking, ST risks are in the range of 1% or 2%, and possibly less, are most consistent with the epidemiologic evidence. Perhaps most important, our calculation shows that comparative risk estimates as high as 5%, let alone 10% or more, cannot be justified based on the evidence."

Using the risk estimates described in detail above, the following table compares the number of deaths that would occur annually among 45 million ST users with the number of deaths that the CDC estimates among 45 million smokers.

Table 2
Annual Smoking-Attributable Deaths in the United States
45 Million Smokers or 45 Million ST Users

<table>
<thead>
<tr>
<th>Cause of Death</th>
<th>Smokers: Estimated Numbers of Deaths per Year in the United States</th>
<th>Smokeless Tobacco: Estimated Numbers of Deaths per Year in the United States</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Range of RR^x^2</td>
<td>Range of RR^3^</td>
</tr>
<tr>
<td>Cancer</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mouth and throat</td>
<td>5-11</td>
<td>1.0-4.0</td>
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<td>Pancreas</td>
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<td>Lung</td>
<td>13-23</td>
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<td>Other</td>
<td>23,316</td>
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</tr>
<tr>
<td>All Cancer</td>
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<tr>
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<tr>
<td>Cardiovascular</td>
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<tr>
<td>All Environmental Tobacco Smoke</td>
<td>38,000</td>
<td></td>
</tr>
<tr>
<td>All</td>
<td>435,962^x^x^x^x^</td>
<td>2,668</td>
</tr>
</tbody>
</table>

References


23 Grady D, Greene J, Daniels TE et al, 1990. Oral mucosal lesions found in smokeless tobacco users. JADA 121, 117-125


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Whereas # 2 – Elimination of environmental tobacco smoke (ETS) and fire-related hazards

It is obvious, but by no means insignificant, that transitioning smokers to selected ST products will entirely eliminate environmental tobacco smoke and fire-related hazards for both smokers and everyone else. According to the U.S. Environmental Protection Agency, ETS is responsible for 150,000–300,000 new cases of bronchitis and pneumonia in children aged less than 18 months, resulting in 3,500–12,500 hospitalizations, annually [1]. The California Environmental Protection Agency estimates that ETS causes approximately 3,000 lung cancer deaths and 35,000 heart disease deaths annually among adult nonsmokers in the United States [2].

In February of 2008, the European Commission released a report on the health effects of ST products that included the following statement:

"Since ST products do not produce smoke they will not cause any of the health problems linked to passive smoke exposure in adults or children. Substitution of intranasal tobacco would therefore prevent the passive smoke-related diseases." [3]

References


Whereas # 3 – “Abstain, quit, or die” may have reached maximum achievable benefit

In a 2007 commentary published in the Lancet, Foulds and Kozlowski noted that:

“Around a billion people are addicted to nicotine in deadly cigarettes and many have no immediate plans to quit. Young people will also continue to try dangerous and addictive products. We believe it is preferable that, if people become addicted to cigarettes or decide to try tobacco, they can use a product that is markedly less harmful than cigarettes. In Sweden, primary use of [ST] is associated with reduced risk of cigarette smoking in adulthood. The Lancet papers published today, when added to mounting epidemiological evidence, indicate that we should not delay in allowing [ST] to compete with cigarettes for market share, and we should be prepared to accurately inform smokers about the relative risks of cigarettes, [ST], and approved smoking-cessation medications. In light of all the available evidence, the banning or exaggerated opposition to [ST] in cigarette-free environments is not sound public-health policy." [1]

In a 2008 Lancet article, Britton and Edwards lamented the lack of progress against smoking and urged governments to incorporate tobacco harm reduction into tobacco regulatory frameworks:

“In the 50 years since the health risks of smoking first became widely recognized, the political and public health responses to smoking at national and international levels have been grossly inadequate… A logical harm reduction approach for the millions of smokers who are unlikely to achieve complete abstinence in the short-term or medium-term future is to promote the substitution of tobacco smoking with an alternative, less hazardous means of obtaining nicotine. We believe that the absence of effective harm reduction strategies for smokers is perverse, unjust, and acts against the rights and best interests of smokers and the public health. The regulatory framework should therefore apply the levers of affordability, promotion, and availability in direct inverse relation to the hazard of the product, thus creating the most favourable market environment for the least hazardous products while also strongly discouraging use of smoked tobacco." [2]

Sweeney et al. assessed the global public health implications of tobacco harm reduction in a 2007 article in the International Journal of Drug Policy:

“We rate the world’s 1.3 billion cigarette smokers acquiring their nicotine from clean delivery systems rather than through repeated inhalation of smoke, nicotine use would likely not rank much higher than caffeine use as a public health priority. The consumer who rejects (or cannot achieve) abstinence but will use a product that reduces risk by 90% should not be prevented from making that preferred choice. Indeed, it is exactly the forced choice between smoking and abstinence that reinforces the current dominance of cigarettes. The relative safety of ST and other smokefree systems for delivering nicotine demolishes the claim that abstinence-only approaches to tobacco are rational public health campaigns. Applying harm reduction principles to public health policies on tobacco/nicotine is more than simply a rational and humane policy. It is more than a pragmatic response to a market that is, anyway, already in the process of undergoing significant changes. It has the potential to lead to one of the greatest public health breakthroughs in human history by fundamentally changing the forecast of a billion cigarette-caused deaths this century.” [3]
Whereas #4 – Harm Reduction works and can be accomplished in a way that will not increase initiation or decrease cessation

Evidence that ST is an Effective Substitute for Cigarettes

In 2008 Rodu and Phillips provided the first population-level evidence that over a quarter of a million American men have quit smoking by switching to ST [1]. The study showed that switching to ST resulted in over twice the proportion of former smokers (73%) than the nicotine patch (35%), gum (34%), inhaler (28%) or nasal spray (0%). It is particularly striking that an estimated 359,000 smokers tried to stop smoking by switching to ST – and over a quarter of a million became former smokers – especially since Americans are largely misinformed about the health risks of ST use [2,3]. It is safe to assume that rates of switching would increase substantially if smokers knew that switching to ST achieves almost all of the health benefits as quitting tobacco and nicotine altogether [4].

The comparison between ST and pharmaceutical nicotine also proves enlightening, especially in a broad social context. Nicotine gum and the nicotine patch have been available since 1984 and 1992 respectively [5]. Both products achieved non-prescription status in 1996, and that year the manufacturer conducted a large promotional campaign in conjunction with the ACS Great American Smokeout [6]. In 1999 an estimated $200 million was spent on print and broadcast advertising for smoking cessation products [7].

In contrast to the heavy promotion and advertising of pharmaceutical nicotine products for smoking cessation in the late 1990s, the environment for ST products was quite negative. A ban on broadcast advertising of ST had been established as early as 1986 [8], so the estimated $170 million spent on advertising in 1999 was restricted largely to print media [9]. Not only were manufacturers effectively prohibited from offering ST products as reduced-risk options for smokers, a counter-marketing program was launched by congressional legislation in 1986, in the form of one of three mandatory warning statements on every package of ST sold in the U.S. “This product is not a safe alternative to cigarettes” [8]. In addition, major efforts have been made by the American tobacco control community to impede any widespread transition from cigarettes to ST [2,3]. Despite the pro-pharmaceutical and anti-ST climate, an estimated 261,000 men had used smokeless tobacco to quit smoking by the year 2000. While this number is lower than the number who had successfully used the nicotine patch (about one million), it is comparable to the number who had successfully used either nicotine gum or antidepressants, and far more than the number who were successful with other pharmaceutical nicotine products.

Unfortunately, no information on switching to ST is available in subsequent NHIS surveys, because that option was removed when the Cancer Control module next appeared, in the 2005 NHIS [10].

One clinical trial, an open-label, nonrandomized pilot study, has been conducted assessing the efficacy of an ST product in helping cigarette smokers become smoke-free. The investigators used a low-intensity approach, consisting of a 20-minute lecture about the health effects of all forms of tobacco use, followed by information about and samples of pre-portioned single-dose tobacco packets available throughout the U.S. The investigators used exhaled carbon monoxide levels to validate participant self-reports regarding smoke-free status at the conclusion of the original study after one year [11] and after seven years of follow-up [12].
Of 63 subjects starting the study, 16 had successfully quit smoking by switching to ST after one year, and 12 were still smoke-free after seven years. At enrollment, the average cigarette consumption of the successful participants had been 1.5 packs per day. One year later average consumption of ST was 2.6 packages per week among the 13 successful quitters using ST (3 were tobacco-free). Four additional participants had used ST to reduce their cigarette consumption by at least 50%.

For the past 100 years, cigarette smoking has been the dominant form of tobacco consumption in almost all developed countries. One notable exception is Sweden, where smoking rates, especially among men, have been considerably lower than those of comparable countries for decades. (An ACSH article provides historical background on Swedish snuff [13].) Over the past 50 years Swedish men have had the lowest rates of smoking-related cancers of the lung, larynx, mouth and bladder in Europe [14], and the lowest percentage of male deaths related to smoking of all developed countries [15,16].

A 2004 study revealed that if men in the (15-country) EU had the smoking prevalence of Sweden, almost 200,000 deaths attributable to smoking would be avoided each year [17]. In contrast, women in Sweden smoke at rates similar to women in other European countries. This is reflected in similar rates of smoking-related illnesses among women.

As Fagerström pointed out in a recent study, per capita consumption of nicotine from tobacco in Sweden is quite high and on par with other countries such as Denmark, the U.S. and Austria [18]. The difference between Sweden and the other countries is how nicotine is consumed. In Denmark, the U.S. and Austria, almost all nicotine consumption is derived from tobacco combustion. In contrast, ST use, in the form of snus, accounts for almost 50% of all contemporary nicotine consumption in Sweden. Snus use in Sweden is much more common among men than among women; over 60% of nicotine consumption among Swedish men is from snus. This is not a new phenomenon; for over a century, Swedish men have had among the world’s highest per capita consumption of ST [19].

Beginning in 2002, an American-Swedish research group used a World Health Organization database to describe in detail the impact of snus use on smoking among the population in northern Sweden during the period 1986-2004 [20-22].

Among men, the prevalence of all tobacco use was stable during the study period, at about 40%. However, there were striking, and opposite, changes in prevalence of smoking and snus use. Smoking prevalence was 19% in 1986, and it was lower in all subsequent surveys, reaching 9% in 2004. The prevalence of exclusive snus use increased from 18% in 1986 to 27% by 2004. Snus use was the dominant factor in the higher prevalence of ex-smokers among men compared to women (prevalence ratio 6.18, 95% CI 4.96 – 7.70). (In other words, men were 6.18 times more likely than the women to be ex-smokers; CI = “confidence interval” This means that if we could have gathered data from all the men in Northern Sweden, there is a 95% chance the prevalence ratio would have been between 4.96 and 7.70.)

Among women the prevalence of tobacco use also was steady at 27 to 28%, and women smoked at higher rates than men in all surveys. But these studies showed that snus use was associated with lower smoking rates among women in 1999 and 2004. Smoking prevalence was about 25 to 27% in

Evidence that Harm Reduction Will Not Increase Initiation

Data from research studies in Sweden and the U.S. do not show that widespread use of ST serves as a gateway to smoking, especially among youth. A 2003 policy statement published in Tobacco Control, coauthored by Clive Bates, former director of Action on Smoking and Health (U.K.) and five other eminent tobacco research and policy experts, dismissed the notion that ST use led to smoking in Sweden: “To the extent there is a ‘gateway’ it appears not to lead to smoking, but away from it and is an important reason why Sweden has the lowest rates of tobacco related disease in Europe” [27]. Foulds reached a similar conclusion: “This review suggests… that in Sweden snus has served as a pathway from smoking, rather than a gateway to smoking among Swedish men” [28].

A 2005 study examined tobacco use among 15- to 16-year old schoolchildren in Sweden over a 15-year period, from 1989 to 2003 [29]. The investigators found that the prevalence of regular snus use among Swedish boys increased from about 10% to 13% from 1989 to 2003, but the prevalence of regular smoking was very low and declined, from about 10% to under 4%. The prevalence of snus use among girls was very low, and the prevalence of smoking was about double that of boys
over the entire period. The authors concluded that snus use did not appear to be a gateway to smoking among Swedish youth but instead was associated with low smoking prevalence among boys.

Other recent studies based in Sweden have come to similar conclusions. In 2005 Furberg et al. investigated whether snus use was associated with smoking initiation or smoking cessation using data from the population-based Swedish Twin Registry. They concluded that snus use was "inversely associated with initiation." [30]

In 2006 Ramström and Foulds examined data on tobacco use from a national Swedish survey. They found that "Use of snus in Sweden is associated with a reduced risk of becoming a daily smoker." [31] With respect to these findings, the European Commission’s Scientific Committee on Emerging and Newly Identified Health Risks concluded that "The Swedish data do not support the hypothesis that…snus is a gateway to future smoking." [32]

In the U.S., concurrent use of cigarettes is common among ST users [33]. However, investigators have not found credible evidence that ST use is a gateway to smoking among American youth. In 2003 Kozlowski et al. analyzed data from the 1987 NHIS survey and concluded that there was little evidence that ST use was a gateway to smoking, because the majority of ST users had never smoked or had smoked cigarettes prior to using ST [34]. The investigators noted that their results concurred with earlier work from Sweden and with a tobacco industry-sponsored survey from 1984 [35].

In 2003 O’Connor et al. examined data from the 2000 National Household Survey on Drug Abuse [36]. They described the impact of ST use on subsequent cigarette smoking initiation as "minimal at best." O’Connor et al. also examined data from the CDC’s Teenage Attitudes and Practices Survey for evidence that ST use served as a gateway to smoking among youth [37]. They concluded that ST use was not associated with smoking initiation with appropriate control for confounding by well-recognized psychosocial predictors of smoking. This is in contrast to an earlier report that did not control for confounding and found a positive association [38].

Claims of a gateway effect persist, even with lack of credible evidence, prompting O’Connor et al. to note in 2005, "Continued evasion of the [harm reduction] issue based on claims that ST can cause smoking seems, to us, to be an unethical violation of the human right to honest, health-relevant information." [39].

References


Whereas #5 -- Agencies and Organizations endorsing harm reduction

In 2002 Britain's Royal College of Physicians, one of the world's most prestigious medical societies, issued a report on tobacco regulation in the United Kingdom called "Protecting Smokers, Saving Lives." [1] As noted earlier, this report stated "At a way of using nicotine, the consumption of non-combustible [smokeless] tobacco is on the order of 10-1,000 times less hazardous than smoking, depending on the product." The report continued with an implicit endorsement of tobacco harm reduction, acknowledging that some smokeless manufacturers may want to market their products "as a 'harm reduction' option for nicotine users, and they may find support for that in the public health community." In 2007 the Royal College issued an even stronger endorsement of tobacco harm reduction [2]. The report concluded:

"...that smokers smoke predominantly for nicotine, that nicotine itself is not especially hazardous, and that nicotine could be provided in a form that is acceptable and effective as a cigarette substitute, millions of lives could be saved... Harm reduction is a fundamental component of many aspects of medicine and indeed, everyday life, yet for some reason effective harm reduction principles have not been applied to tobacco smoking." The report read.

"Compiled by leading experts in the field, this report makes the case for harm reduction strategies to protect smokers. It demonstrates that tobacco smoke predominately for nicotine, that nicotine itself is not especially hazardous, and that nicotine could be provided in a form that is acceptable and effective as a cigarette substitute, millions of lives could be saved... Harm reduction is a fundamental component of many aspects of medicine and indeed, everyday life, yet for some reason effective harm reduction principles have not been applied to tobacco smoking." The report reads again.

In 2006 the American Council on Science and Health (ACSH) became the first American organization to endorse tobacco harm reduction. ACSH has been a recognized leader of tobacco control for several decades. And it has held the tobacco industry accountable for its part of the devastating toll from tobacco. ACSH founder Elizabeth Whelan published a landmark anti-smoking book, A Smoking Gun?: How the Tobacco Industry Gets Away with Murder [3]. The mission of the ACSH is to promote sound science in regulation, in public policy, and in the courtroom to assist consumers, via the media, in distinguishing real health threats from purely hypothetical ones. ACSH believes that strong support of tobacco harm reduction is fully consistent with this mission; there is a strong scientific and medical foundation for tobacco harm reduction, and it shows great potential as a public health strategy to help millions of smokers.

References


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Whereas #6 – Incorrect Impression of equal risk

Americans are badly misinformed about the risks of ST use, especially in comparison with smoking. In 2005 a survey of 2,028 adult U.S. smokers found that only 10.7% correctly believed that ST products are less hazardous than cigarettes [1]. In another survey, 82% of U.S. smokers incorrectly believed that chewing tobacco is just as likely to cause cancer as smoking cigarettes [2]. A 1999-2000 survey of 36,012 young adults entering the U.S. Air Force found that 75% of males and 81% of females incorrectly believed that switching from cigarettes to ST would not result in any risk reduction, while another 16% of males and 13% of females incorrectly believed that only a small risk reduction would occur. Only 2% of males and 1% of females correctly understood that a large risk reduction would occur by switching from cigarettes to ST [3]. That survey also found that the overwhelming majority of subjects believed that switching from regular to low-tar cigarettes conferred greater reduction in risks than switching from cigarettes to ST.

It is not clear how Americans have become so confused about tobacco risks. But it is clear that misinformation about ST products is available in copious quantities from ostensibly reputable sources, including governmental health agencies and health-oriented organizations. Phillips et al have made some of the most pointed comments about this phenomenon:

“Certain health advocates believe it is acceptable to mislead people into making choices they would not otherwise make. Through the use of various tactics, advocates who oppose the use of ST as a harm reduction tool have managed to convince most people that the health risk from ST is several orders of magnitude greater than it really is. The primary tactic they use is making false or misleading scientific claims that suggest that all tobacco use is the same. Apparently motivated by their hatred of all things tobacco, they are trying to convince people not to switch from an extremely unhealthy behavior to an alternative behavior that eliminates almost all of their risk” [4].

The tactic has worked in the U.S., as Americans, almost without exception and regardless of general and health education levels, believe that the risks from ST are similar to those from smoking. In particular, Americans incorrectly believe that switching from smoking to ST use will create a large increased risk for oral cancer. Phillips has characterized this popular misinformation as the “you might as well smoke” message, since it tells people that if they are using ST, they could switch to smoking with no increase in risk, while smokers considering switching to ST should not bother [5].

Phillips et al. systematically reviewed content about ST use on the web in 2003 and found that the risks of ST use are almost always conflated with those of smoking [6]. Roughly one-third of the time, there are explicit claims that ST is as bad as or worse than smoking. Most of the rest of the time the information is arranged to imply similar risks, though there is no such explicit statement. There are also a variety of specific claims that are not supported by the literature.

Government agencies, other organizations and members of the public health community have a moral obligation not to misinform smokers about products that have fewer risks than cigarettes. Nevertheless, researchers have exposed numerous cases of misinformation from governmental sources. For example, in 2003 Kozlowski and O’Connor criticized websites of the CDC and the Substance Abuse and Mental Health Services Administration for erroneously reporting that ST products were not safer than cigarettes, pointing out that “the misleading health information on ST fails to meet the government criteria against deception in research” [6].

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At a 2003 U.S. House subcommittee hearing, U.S. Surgeon General Richard Carmona testified: “I cannot conclude that the use of any tobacco product is a safer alternative to smoking. There is no significant evidence that suggests ST is a safer alternative to cigarettes.” [7] Scott Leshow, at that time the Chief of the Tobacco Control Research Branch at the NCI, presented similar testimony at a concurrent hearing [8]. Carmona’s statement prompted Rodu, who also presented testimony at that hearing [9], to comment that the Surgeon General was “sadly ill-informed about the nation’s No. 1 health problem, cigarette smoking.” Rodu strongly criticized Carmona, writing that he should be compelled to “tell American smokers the truth about all available options for quitting. After all, the 10 million smokers who will die over the next two decades are, in a tangible way, his responsibility and his legacy” [10].

In March 2004, Ken Boehm of the National Legal & Policy Center (NLPC), a non-profit organization committed to promoting open, accountable and ethical practices in government, filed a request under the Data Quality Act (DQA) for correction of a document from the National Institute of Aging (NIA) that contained misinformation regarding the relative risks of ST versus cigarettes (This other DQA requests on ST can be seen at the U.S. Department of Health and Human Services website [11]). The request resulted in a change of wording from the original text: “Some people think ST (chewing tobacco and snuff), pipes, and cigars are safer than cigarettes. They are not.” The revised wording from NIA was: “Some people think ST (chewing tobacco and snuff), pipes, and cigars are safer than cigarettes. They are not.”

The claim that ST products are not “safe” is a tactic that can be traced back to the 1986 Comprehensive Smokeless Tobacco Education Act, which required as one of three warnings on all ST products: “This product is not a safe alternative to cigarettes.” In 1995 Rodu criticized this warning as ludicrous and suggested that other consumer products like automobiles, lawnmowers, aspirin and red meat don’t meet absolute criteria for safety [12]. A decade later, Kozlowski and Edwards criticized this type of uninformative warning in a study entitled, “‘Not safe’ is not enough: smokers have a right to know more than there is no safe tobacco product” [13]. These authors believe that smokers deserve more information:

“The ‘not safe’ or ‘not harmless’ messages don’t address the reality that some tobacco products are substantially safer than others. Saying tobacco isn’t safe isn’t incorrect, but it isn’t saying enough. Going beyond the no safe tobacco message to provide better information on the nature of risks from tobacco products and nicotine delivery systems is necessary to respect individual rights to health relevant information.”

Ken Boehm from NLPC summarized the arguments against misinformation:

“This is the kind of evidence Americans should be able to review and make their own decisions. Despite the best efforts of the largest government bureaucracy in the history of the republic, Americans still prefer to do their own thinking. And as we do our own thinking on the merits of reduced-risk products such as ST, none of us needs misinformation supplied by our own government” [14].

References
Whereas # 7 – Tax policy

Excise taxes represent a potentially valuable tool for tobacco harm reduction. In 2005, Kentucky Governor Ernie Fletcher described the rationale for a differential tax on ST products in comparison to cigarettes that reflects risk differences:

"Increasing taxes on tobacco products should have a deterring effect on their use, and therefore result in healthier lifestyles for Kentuckians. The relative taxes on tobacco products in this proposal reflect the growing data from scientific studies that although ST poses some risk, those health risks are significantly less than other forms of tobacco products. It also acknowledges that some in the public health community recognize that tobacco harm reduction should be a complementary strategy to any public health policy toward tobacco products. Taxing tobacco products according to relative risks is a rational tax policy and may well serve the public health goal of reducing smoking-related mortality and morbidity and lowering health care costs associated with tobacco-related disease." [1]

This tax policy was enacted by the General Assembly of the Commonwealth of Kentucky in 2005 (KRS CHAPTER 136). In 2006 the American Council on Science and Health noted that “State legislatures should place higher taxes on more dangerous tobacco products than on less dangerous tobacco products. The state of Kentucky has already taken steps in this direction.” [2] The Heartland Institute commented that “Another harm reduction strategy often recommended is that in recognition of ST’s lesser risks, taxes to discourage tobacco use should focus on cigarettes, not ST. That approach is gaining some acceptance.” [3]

Gartner and Hall, writing in PLoS Medicine in 2007, endorsed this concept: “[T]here is a strong prima facie case on public health and ethical grounds for recommending [ST] to invertebrate smokers who want to reduce their health risks and for considering public policies (such as lower taxes for [ST] and public information campaigns) to promote its use by smokers.” [4] In 2008 these Australian tobacco researchers urged their government to “reduce the absurdly high customs tax on ST products to make [them] more affordable and easier to import.” [5]

In 2007 the National Center for Policy Analysis issued a report on excise taxation of tobacco, alcohol, gambling and other products, which noted the irrational tobacco excise taxes in some states:

"If the true purpose of excise taxes on tobacco products is to recoup the external costs to society, states should levy lower taxes on smokeless products than on cigarettes. However, some states do the reverse. About a fifth of the states charge higher taxes as a percent of the manufacturer’s or wholesale price than for cigarettes, including Massachusetts (90 percent for smokeless products versus 68 percent for cigarettes), Texas (35.2 percent versus 18.5 percent), Minnesota (70 percent versus 55.4 percent), Idaho (40 percent versus 25.7 percent) and Oklahoma (60 percent versus 46.4 percent), to name a few.” [6]

In 2008 the Buckeye Institute for Public Policy Solutions suggested that these irrational tax policies may have unfortunate consequences:

"Illnesses from cigars and ST such as chewing tobacco cost taxpayers almost nothing. These products are just not as dangerous as cigarettes. Because of this, they should have
no special taxes levied on them. While all tobacco products pose some health risk, smoking cigars or using chewing tobacco causes far fewer health problems than smoking cigarettes. By raising the cost of these less dangerous products the anti-tobacco activists may well cause some people who used these products to satisfy their tobacco habit with cigarettes.”[7]

In 2007, Kozlowski concluded that “The reviewed evidence indicates that ST products as effective nicotine-delivery systems can function as cigarette substitutes and cessation aids.” He advocated for implementation of harm reduction using tax policy. “Econometric research indicates that if one desires the maximum reduction in cigarette sales with a tax increase on cigarettes, it is also important to make other substitutable nicotine-delivery systems (nicotine replacement therapy) and ST cost less than cigarettes.”[8]

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Whereas # 8 – Political and financial viability of harm reduction

The tobacco industry and tobacco-related stakeholders are not of one mind, and do not speak with a single voice. The traditional practice within the medical and public health communities of considering cigarettes and the major cigarette companies as emblematic of the entire tobacco industry and all industry-related stakeholders is simply incorrect. Personal experience over a period of decades in dealing with these stakeholders has left one of us (JLN) with the impression that they are a very diverse group, highly competitive within their various market niches, and, as a general rule, intensely dislike of Altria/Philip Morris — the makers of Marlboro Cigarettes is widely prevalent.

Scott D. Ballin, JD, in his role as Tobacco and Health Policy Consultant for the Alliance for Health Economic and Agricultural Development (AHEAD), has been, more than any other single individual, an advocate for productive dialogue between public health advocates, growers, and other tobacco-industry-related stakeholders. In his October 3, 2007 testimony to the House Health Committee Subcommittee on Energy and Commerce, he described the mission of AHEAD in the following terms:

“The Alliance is an informal organization whose purpose is to educate, stimulate, and facilitate discussions with and between public health advocates, growers, the scientific community, tobacco manufacturers, consumers, policy makers, pharmaceutical and biotech interests about a spectrum of issues related to the production, processing, manufacture, sale, distribution, labeling, marketing and use of tobacco and tobacco products. The Alliance is an outgrowth of the Southern Tobacco Communities Project established in the mid-1990’s through a grant from the Robert Wood Johnson Foundation that brought the public health community and growers together to engage in a civil dialogue about tobacco. That dialogue led to the issuance of a set of Core Principles in 1998 and the presidential commission report Tobacco at a Crossroads in May of 2001. The Steering Committee members serve as individuals, each of whom has significant and unique experiences in dealing with tobacco-related issues."[1]

AHEAD has published a detailed report entitled Tobacco and Tobacco Products At a Crossroads in the 21st Century: Reducing Harm from Tobacco and Tobacco Products; Can Tobacco and Tobacco Product Modification Play a Role? Seeking Civil Solutions in an Uncivil Environment.[2] This report is well worth reading for anyone interested in productive dialogue between the public health community and tobacco-industry stakeholders in pursuit of common objectives under which tobacco industry stakeholders can thrive while protecting the health of the public.

The concept of political and financial viability of a harm-reduction approach is based on the idea that encouraging the use of lower risk tobacco products to reduce tobacco-related illness and death will give growers something to grow, manufacturers and vendors products to manufacture and sell, etc. As noted before, this can be done in a way that will not reduce effectiveness of other programming intended to reduce initiation of tobacco use by children and youth, and not reduce effectiveness of efforts to encourage smokers to quit.

References
Note Regarding Pharmaceutical versus Non-Pharmaceutical Harm Reduction Products

Some writers in this field feel that harm-reduction nicotine delivery products should be limited to "medicinal nicotine" products produced by or on behalf of pharmaceutical firms. [1]

We disagree. It is our opinion that, if such products are to effectively reach populations at highest risk for cigarette-related illness and death—high school dropouts, disadvantaged minorities, gays, and others—products will have to be accessible through the same retail outlets that sell cigarettes, and at comparable prices.


Note on the Need for Additional Research

The prevailing public health policy that could be summarized with the phrase "avoid all use of tobacco products: abstain, quit or die" has sorely inhibited research into many topics related to tobacco and health. It has created a situation in which company-sponsored research is always suspected of major bias, and government-sponsored research has been largely limited to studies that support the impression that all tobacco use is so harmful that none should be considered.

As a result, the best we can do is to extrapolate the expected hazards from other forms of smoking tobacco products (cigars, pipes, water pipes, etc.) to be similar in risk to cigarettes, and seriously question the public health value and impact of inhalable nicotine products being marketed or developed as harm-reduction alternatives. While snus has an enviable track record of safety over many decades of use in Scandinavian countries, there is no such track record for many of the non-pharmaceutical nicotine delivery devices now either on the market or coming to market.

The only practical means by which the needed research can be done will be the passage of federal legislation for federal oversight of tobacco products that realistically recognizes both the prevalence and power of the addictiveness of nicotine and a willingness to consider all feasible options to reduce tobacco-related illness and death. Such legislation should include provision by which one or more funds can be developed that will enable governmental sponsorship of unbiased research into all possible approaches to reducing tobacco-related illness and death.

That having been said, it is important to repeat the perception by the authors of this paper and the organizations supporting the resolution herein—that currently available scientific findings are more than adequate to vigorously pursue harm reduction as one aspect of our continuing efforts to reduce tobacco-related illness and death. We do not need more research to justify such an approach. What we need is new legislation and policy and program development to translate this knowledge into effective public health programming, while we pursue additional research to further refine our public health efforts.

Bios and Financial Disclosure Statements

Joel L. Nitzkin, MD, MPH, DPA, FACPM, is a public health physician who has spent most of his career working for local and state health departments. Following graduation from medical school in 1966, he had a one-year rotating internship at Parklawn Memorial Hospital, in Dallas, TX, followed by a two-year tour of duty in the CDC’s Epidemic Intelligence Service. In 1970 he secured a Master’s Degree in Public Health from the University of California at Berkeley. From 1970 to 1976 he directed the communicable and chronic disease programming at the Dade County Health Department, in Miami, Florida. While there he completed his credentialing in the medical specialty of Preventive Medicine and pursued his Master’s Degree and Doctorate in Public Administration at Nova University, in Fort Lauderdale. From 1976 to 1989 he served as Director of the Monroe County Health Department, in Rochester, New York. It was while in Rochester that Dr. Nitzkin became deeply involved in tobacco control as a public health priority, with Monroe County adopting what was, in its time (1983), one of the strictest clean indoor air ordinances. From 1989 to 1992, Dr. Nitzkin served as the Assistant Secretary for Public Health (State Health Officer) for the state of Louisiana. Since 1992, he has been in the private practice of public health as policy consultant. For four of these years he was full time faculty at the LSU School of Medicine as follow-through to a consulting project. Since the late 1990’s Dr. Nitzkin has served as the Chair of the Tobacco Control Task Force of the American Association of Public Health Physicians. Dr. Nitzkin has never sought nor secured any financial or other support from any tobacco-related enterprise.

Brad Rodu, DDS, is Professor of Medicine and holds an Endowed Chair, Tobacco Harm Reduction Research, School of Medicine at the University of Louisville in Kentucky. An oral and maxillofacial pathologist by training, he was on the faculty at the University of Alabama at Birmingham (UAB) from 1981 to 2005, with appointments in several departments in the Schools of Medicine, Public Health and Dentistry.

For the past 15 years Dr. Rodu’s research has focused on tobacco harm reduction, including prevalence studies of tobacco use, epidemiologic models of the health risks and life expectancy of tobacco users, and laboratory analyses of tobacco products. He also conducted research in Sweden, where tobacco harm reduction has been realized and has resulted in a profound effect on public health. His research has been published in a broad range of medical and scientific journals such as Nature, The American Journal of Medicine, Epidemiology, Cancer Journal of Clinical Oncology, Nicotine and Tobacco Research and Tobacco Control.

From 1993 to 1999 Dr. Rodu’s research on tobacco harm reduction was conducted with only very limited financial support from general accounts at UAB, and no external support whatsoever. During that time Dr. Rodu and his colleagues established the scientific foundation of tobacco harm reduction with publications in professional medical journals and in the general press.

From 1999 to 2005 UAB Dr. Rodu’s research was supported by a research grant from the United States Smokeless Tobacco Company (USSTC) of Greenwich, Connecticut to UAB. The agreement between USSTC and UAB broke new ground with regard to industry-sponsored university research. The award was completely unrestricted; the agreement specified that UAB had no obligation to USSTC regarding consequential work products. The grantor had no scientific input or other influence regarding the nature of the research projects or activities and did not have access to
research reports prior to their publication. In other words, the structure of this agreement exceeded UAB guidelines with regard to financial support from external sources, and it imposed absolutely no restrictions on academic freedom in the undertaking and communication of funded research. A scientific advisory board oversaw the program.

In 2005 Dr. Rodi joined the University of Louisville. Financial support for the endowed chair and research activities was made possible by grants from USSTC and Swedish Match (based in Stockholm, Sweden with North American operations based in Richmond, Virginia). These grants are also unrestricted, which ensures the scientific independence and integrity of research projects and activities. The chair was also funded in part by the State of Kentucky Research Challenge Trust Fund, a program that makes it possible for public universities in Kentucky to attract and retain the nation’s top scholars and researchers.
Switching to smokeless tobacco as a smoking cessation method: evidence from the 2000 National Health Interview Survey
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Abstract

Background: Although smokeless tobacco (ST) use has played a major role in the low smoking prevalence among Swedish men, there is little information at the population level about ST as a smoking cessation aid in the U.S.

Methods: We used the 2000 National Health Interview Survey to derive population estimates for the number of smokers who had tried twelve methods in their most recent quit attempt, and for the numbers and proportions who were former or current smokers at the time of the survey.

Results: An estimated 359,000 men switched to smokeless tobacco in their most recent quit attempt. This method had the highest proportion of successes among those attempting it (73%), representing 261,000 successful quitters (switchers). In comparison, the nicotine patch was used by an estimated 2.9 million men in their most recent quit attempt, and almost one million (35%) were former smokers at the time of the survey. Of the 964,000 men using nicotine gum, about 323,000 (34%) became former smokers. Of the 98,000 men who used the nicotine inhaler, 27,000 quit successfully (28%). None of the estimated 14,000 men who tried the nicotine nasal spray became former smokers.

Forty-two percent of switchers also reported quitting smoking all at once, which was higher than among former smokers who used medications (8–19%). Although 40% of switchers quit smoking less than 5 years before the survey, 21% quit over 20 years earlier. Forty-six percent of switchers were current ST users at the time of the survey.

Conclusion: Switching to ST compares very favorably with pharmaceutical nicotine as a quit-smoking aid among American men, despite the fact that few smokers know that the switch provides almost all of the health benefits of complete tobacco abstinence. The results of this study show that tobacco harm reduction is a viable cessation option for American smokers.

Background

For the past half century men in Sweden have had among the lowest rates of smoking – and the lowest rates of smoking-related illnesses – in the developed world [1]. Several recent studies have shown that the high prevalence of smokeless tobacco (ST) use among Swedish men has played a substantial role in the remarkably low smoking prevalence, mainly in two ways. First, the popularity of ST
among Swedish men suppresses smoking initiation [2-4]. More importantly, substituting ST facilitates risk reduction by allowing smokers to become smoke-free without abstaining from tobacco and nicotine altogether [3-6], but complete abstinence is still achievable [4,7]. There is now evidence that ST use has started to become popular among Swedish women as well, with similar effects on smoking rates [4,8]. Tobacco harm reduction, which actively encourages invertebrate smokers to switch to safer sources of nicotine including ST, is increasingly seen as a promising public health intervention [9-11].

Like Sweden, the U.S. is one of the few Western countries with measurable ST use. According to the National Health Interview Survey (NHIS), the prevalence of ST use among men in the U.S. was 4.5% in the year 2000 [12]. However, in contrast to Sweden, there are only anecdotal reports of ST use for smoking cessation in the U.S [13]. In fact, few resources provide information about cessation at the population level, especially with respect to ST use.

One recent article briefly mentioned that the 2000 NHIS collected information on ST use as a quit-smoking method [14]. However, the information in that article was very selective (1.2% of male former smokers age 36-47 years had switched to snuff or chewing tobacco in order to quit smoking), and it provided little perspective on how switching to ST compared with other cessation methods.

In fact, the 2000 NHIS collected information on 12 methods used by smokers in their most recent quit attempt and who subsequently either quit smoking successfully (former smokers at the time of the survey) or had failed to quit (current smokers). This study uses that survey to estimate the number of male smokers in the U.S. that used various cessation methods.

Methods

We obtained the 2000 NHIS Adult Sample and Cancer Control Module data files from the Inter-University Consortium for Political and Social Research [15]. Our study focused mainly on men, because in 2000 the prevalence of ST use among women was too low (0.3%)[12] to provide reliable information. However, we generated point estimates of switching to ST among women for comparison.

Subjects who had smoked ≥ 100 cigarettes in their lifetime and who smoked every day or some days were classified as current smokers, while subjects who had smoked ≥ 100 cigarettes in their lifetime and who did not currently smoke were classified as former smokers [16]. Subjects who had used chewing tobacco or snuff 20 times in their life and who used either tobacco product every day or some days were classified as current smokeless tobacco users, while subjects who had used either product 20 times in their life and who did not currently use ST were classified as former users [12]. The cancer control module also asked subjects if they had ever used chewing tobacco or snuff.

In the cancer control module, 3,622 male current smokers were asked: "Have you ever stopped smoking for one day or longer because you were trying to quit smoking?" Those answering "no" (n = 1,325, 37%) were excluded from further analysis regarding cessation attempts. The remaining 2,297 smokers were asked: "The last time you stopped smoking, which of these methods did you use?" Subjects were prompted to "mark all [of the following methods] that apply": (1) stopped all at once (cold turkey), (2) gradually decreased the number of cigarettes smoked in a day, (3) instructions in a pamphlet or book, (4) one-on-one counseling, (5) stop-smoking clinic or program, (6) nicotine patch, (7) nicotine containing gum (such as Nicorette), (8) nicotine nasal spray, (9) nicotine inhaler, (10) Zyban/Bupropion/Wellbutrin medication (abbreviated bupropion here), (11) switched to chewing tobacco or snuff (ST here), and (12) any other method. Information about methods was obtained from 2,180 (95%) of the current smokers who had ever tried to quit. In similar fashion, 3,653 former smokers were asked: "When you stopped smoking completely, which of these methods did you use?" followed by the same choices. Information about methods was obtained from 3,548 former smokers (98%).

We identified the quit methods that are endorsed in the Clinical Practice Guideline (CPG) from the Public Health Service, U.S. Department of Health and Human Services [17]. The survey asked former smokers how long ago they had quit, and we classified these subjects into four groups based on the number of years since quitting: 0-4, 5-14, 15-19 and 20+. Because subjects could select more than one method, the results reported here are not mutually exclusive.

The 2000 NHIS employed a complex design involving stratification, clustering and multistage sampling. We used SPSS statistical software with Complex Samples (Version 15.0 for Windows) to provide estimates, based on the non-institutionalized civilian population of the U.S. of the quit-smoking methods used by the 24.0 million men who had successfully quit smoking (former smokers), and by the 15.1 million men who had attempted to quit but were unsuccessful on their last attempt (current smokers).

Results

Table 1 provides the number of male survey respondents who had used various methods in their most recent quit attempt and the percentages who were former and current
smokers at the time of the survey. An estimated 33 million men reported stopping all at once in their most recent quit attempt; almost 21 million (64%) were former smokers at the time of the survey. Of the 2.9 million men who tried to gradually decrease the number of cigarettes that they smoked, 1.3 million (45%) had become former smokers. Of the 76,000 men following instructions in a pamphlet or book, 28% (21,000) became former smokers.

An estimated 359,000 men switched to ST in their most recent quit attempt, and 73% of them (261,000) were former smokers. In comparison, only 42,000 women switched to ST in their most recent quit attempt, and only 38% of them (16,000) were former smokers at the time of the survey.

Among CPG-endorsed methods, the nicotine patch was used by the largest number of men (estimate, 2.9 million) in their most recent quit attempt, and almost 1 million (35%) were former smokers at the time of the survey. An estimated 1.1 million men used bupropion, and 308,000 (29%) were former smokers. Of the 964,000 men using nicotine gum in their most recent quit attempt, about 323,000 (34%) became former smokers. A stop-smoking clinic/program was used by an estimated 311,000 men, 50% of whom (155,000) became former smokers, the highest proportion among CPG-endorsed methods. Of the estimated 107,000 men who used one-on-one counseling, 45,000 became former smokers (43%). Of the 98,000 men who used the nicotine inhaler in their most recent quit attempt, 27,000 quit successfully (28%). None of the estimated 14,000 men who used the nicotine nasal spray became former smokers. An estimated 1.3 million men used other, unspecified methods in their most recent quit attempt, and 817,000 (63%) became former smokers.

We conducted additional analyses restricted to male former smokers who had quit by using the nicotine patch, nicotine gum, bupropion or by switching to ST (hereafter referred to as switchers), in order to provide a better comparison of these methods. For clarity, we use actual survey numbers and unweighted proportions when reporting these findings. Table 2 provides more information about the use of multiple methods by former smokers who quit by using the three medications or ST. Exclusive use of a single method was more common among patch (70%) and bupropion (64%) users than among gum users or switchers (55%). Forty-two percent of switchers also reported stopping all at once, which was higher than for bupropion (8%), nicotine patch (18%) or nicotine gum (19%). Fifteen percent of switchers reported gradually decreasing the number smoked, which was somewhat higher than for bupropion (3%) or the patch (4%). Multiple medication use was more frequent in former smokers who used gum (26%) or bupropion (21%), compared with former smokers who used the patch (10%).

Table 3 shows the distribution of former smokers who used medications or switched to ST, according to the number of years since quitting. Ninety-five percent of bupropion users quit from 0 to 4 years before the survey.
Table 2: Male former smokers who used medications or switched to ST, and their distribution (%) according to other methods used.

<table>
<thead>
<tr>
<th>Method</th>
<th>Nicotine Patch (n = 128)</th>
<th>Nicotine Gum (n = 42)</th>
<th>Bupropion (n = 39)</th>
<th>Switched to ST (n = 33)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stopped all at once</td>
<td>18%</td>
<td>19%</td>
<td>8%</td>
<td>42%</td>
</tr>
<tr>
<td>Gradually decreased cigarettes smoked</td>
<td>4</td>
<td>10</td>
<td>3</td>
<td>15</td>
</tr>
<tr>
<td>Switched to ST</td>
<td>1</td>
<td>5</td>
<td>0</td>
<td>55*</td>
</tr>
<tr>
<td>Pamphlets/book</td>
<td>2</td>
<td>5</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>Nicotine patch</td>
<td>70*</td>
<td>19</td>
<td>13</td>
<td>3</td>
</tr>
<tr>
<td>Bupropion</td>
<td>4</td>
<td>7</td>
<td>64*</td>
<td>0</td>
</tr>
<tr>
<td>Nicotine gum</td>
<td>6</td>
<td>55*</td>
<td>8</td>
<td>6</td>
</tr>
<tr>
<td>Clinic/program</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>One-on-one counseling</td>
<td>0</td>
<td>0</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>Nicotine inhaler</td>
<td>2</td>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Nicotine nasal spray</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Any other method</td>
<td>1</td>
<td>5</td>
<td>10</td>
<td>3</td>
</tr>
</tbody>
</table>

* Percentage of subjects using only that method.

n = unweighted survey count.

ST = smokeless tobacco.

Note: Column percentages total over 100% because some subjects used multiple methods.

while 87% of patch users quit up to 9 years prior to the survey. Although 47% of gum users quit 0–4 years before the survey, the remainder were distributed across the other timeframes, including 20+ years. This pattern was even more evident for switchers, 21% of whom had become former smokers 20+ years prior to the survey.

Because separate sets of survey questions were devoted to smoking cessation and smokeless tobacco use, we were able to obtain information about the latter on the 33 switchers. Fifteen of them (46%) were current ST users at the time of the survey, and twelve (36%) were former users. Of the six that were classified as never users, 3 answered yes to the question about ever use of chewing tobacco or snuff.

**Discussion**

Anecdotal reports have shown that individual smokers have quit smoking by switching to ST [13]. However, this study provides evidence from a nationally representative survey that switching to ST is a viable, although infrequently attempted, quit smoking method for men in the U.S. Of the 261,000 men who switched to ST and became former smokers, about 120,000 (46%) were current ST users at the time of the survey, indicating that the switch may be permanent for some. On the other hand, 54% of switchers did not use any tobacco product at the time of the survey, suggesting that switching to ST is not incompatible with a goal of achieving complete nicotine and tobacco abstinence.

This study shows that switching to ST resulted in over twice the proportion of former smokers (73%) than the nicotine patch (35%), gum (34%), inhaler (28%) or nasal spray (0%). It is important to note that these percentages do not mean that switching to ST is successful 73% of the time or that using pharmaceutical products have a 30% success rate. This type of study cannot answer the question “How often does a particular method work when tried by a particular individual?” The percentages reported for various methods in our study may be substantially different from corresponding answers to this question. The main reason for the distinction is that the NHIS only collected information about the most recent method used. It has no information on the methods used in previous failed quit attempts, or how many times each method was tried.

Table 3: Male former smokers who used medications or switched to ST, and their distribution (%) according to the number of years since quitting.

<table>
<thead>
<tr>
<th>Years Since Quitting</th>
<th>Nicotine Patch (n = 128)</th>
<th>Nicotine Gum (n = 42)</th>
<th>Bupropion (n = 39)</th>
<th>Switched to ST (n = 33)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0–4</td>
<td>60%</td>
<td>47%</td>
<td>95%</td>
<td>40%</td>
</tr>
<tr>
<td>5–9</td>
<td>27</td>
<td>14</td>
<td>0</td>
<td>12</td>
</tr>
<tr>
<td>10–14</td>
<td>11</td>
<td>17</td>
<td>0</td>
<td>18</td>
</tr>
<tr>
<td>15–19</td>
<td>1</td>
<td>17</td>
<td>0</td>
<td>9</td>
</tr>
<tr>
<td>20+</td>
<td>1</td>
<td>5</td>
<td>5</td>
<td>21</td>
</tr>
</tbody>
</table>

n = unweighted survey count.

ST = smokeless tobacco.
Regardless of how one interprets the proportions of former and current smokers, it is particularly striking that an estimated 359,000 smokers tried to stop smoking by switching to ST—and over a quarter of a million became former smokers—especially since Americans are largely misinformed about the health risks of ST use [1,18]. For example, in 2005 a survey of 2,028 adult U.S. smokers found that only 11% correctly believed that ST products are less hazardous than cigarettes [19]. In another survey, 82% of U.S. smokers incorrectly believed that chewing tobacco is just as likely to cause cancer as smoking cigarettes [20]. These findings are in direct contrast to the general agreement among tobacco research and policy experts that ST use is far less hazardous than smoking. Although estimates are not precise, ST use likely confers only 0.1% to 10% of the risks of smoking [21-23].

It is safe to assume that rates of switching would increase substantially if smokers knew that switching to ST achieves almost all of the health benefits as quitting tobacco and nicotine altogether [1]. In 2000 the most likely beneficiaries of this knowledge would have been the 1.1 million American men who were dual users of both cigarettes and ST products. These men were already comfortable consuming nicotine from both combusted and smoke-free tobacco. With the knowledge that ST products were 100 times less hazardous than cigarettes, it is conceivable that most would have chosen exclusive use of ST, resulting in a decline of 1.2 percentage points in national adult male smoking prevalence.

Comparison of ST and pharmaceutical nicotine in a regulatory, legal and social context further suggests that the potential of ST as a cessation aid has been under-realized. Nicotine gum and the nicotine patch have been available since 1984 and 1992 respectively [24], and both achieved non-prescription status in 1996, when the manufacturer conducted a large promotional campaign in conjunction with the American Cancer Society Great American Smokeout [25]. In 1999 an estimated $200 million was spent on print and broadcast advertising for smoking cessation products [26].

In contrast to the heavy promotion and advertising of pharmaceutical nicotine products for smoking cessation in the late 1990s, the environment for ST products was quite negative. A ban on broadcast advertising of ST had been established as early as 1986 [27], so the estimated $170 million spent by manufacturers in 1999 was restricted largely to print media and other forms of advertising and promotion [28]. Not only were manufacturers effectively prohibited from offering ST products as reduced-risk options for smokers, a counter-marketing program was launched by congressional legislation in 1986, in the form of a mandatory warning on every third package of ST sold in the U.S.: "This product is not a safe alternative to cigarettes" [27]. In addition, major efforts have been made by the American tobacco control community to impede any widespread transition from cigarettes to ST [1,18]. Despite the pro-pharmaceutical and anti-ST climate, an estimated 261,000 men had used smokeless tobacco to quit smoking by the year 2000. While this number is lower than the number who had successfully used the nicotine patch (about one million), it is comparable to the number who had successfully used either nicotine gum or antidepressants, and far more than the number who were successful with other pharmaceutical nicotine products.

We expected to find evidence in later surveys that increasing awareness of the low risk profile of modern, socially acceptable ST products would have resulted in heightened popularity for this cessation method. Unfortunately, no information on switching to ST is available in subsequent NHIS surveys, because that option was removed when the Cancer Control module appeared again in the 2005 NHIS [29]. It is possible that individuals responsible for designing the module expected an increase in switching as well, and that they chose to not find out.

A major strength of this study is that it is based on the survey series that the Centers for Disease Control and Prevention (CDC) uses for national smoking prevalence estimates [16]. In fact, our findings were produced from the very same dataset (and specific survey questions) used by the American Cancer Society in a recent study of smoking cessation treatments used by American smokers [30]. Thus, we were surprised when a senior Cancer Society scientist, who was a coauthor on that study [30], stated emphatically that "There is no evidence that smokers will switch to ST products and give up smoking" [31]. Although the Cancer Society has not endorsed tobacco harm reduction, its scientists certainly know that there is unequivocal evidence from the 2000 NHIS survey that 261,000 smokers have switched to ST products in order to quit smoking.

Studies based on survey data are limited by the nature of the survey instrument and the quality of self-reported information. With respect to this survey, current and former smokers were encouraged to choose multiple methods that were not mutually exclusive, which creates some difficulty in reporting the results and may be confusing for some readers. For example, 'Stopped all at once (cold turkey)' was so frequently chosen (with or without other methods) – as would be expected – that all other methods pale in direct comparison. That comparison is certainly confusing, but it may also be inappropriate, since the cold turkey response is orthogonal to the other methods. However, excluding this item would have elim-
inated information that some readers consider useful. Our goal was to present a complete picture of the data, including how frequently all of the methods were chosen.

We noted some inconsistencies among former smokers using medications and switching to ST. For example, among the 128 former smokers who used the nicotine patch, 16 reported that they quit before the patch became available. Two subjects using nicotine gum and two using bupropion had similar inconsistencies. In addition, for three subjects who switched to ST, their responses to other questions indicated no ST use. It is not possible to resolve these irregularities in a systematic manner, but they may affect the certainty of the estimates.

Conclusion
This study documents that switching to ST compares very favorably with pharmaceutical nicotine as a quit-smoking aid among American men, despite the fact that few smokers know that the switch provides almost all of the health benefits of complete tobacco abstinence. As long as American smokers are misinformed about the comparative risks of ST and cigarettes, most will not consider trying to switch, or will do so only reluctantly. A social and public health environment that honestly informs smokers about comparative risks would provide many more smokers with the opportunity to lead longer and healthier lives.

Competing interests
This study was supported by unrestricted grants from smokeless tobacco manufacturers to the University of Louisville (US Smokeless Tobacco Company and Swedish Match AB) and to the University of Alabama (USSTC). The terms of the grants assure that the grantors are unaware of this study, and thus had no scientific input or other influence with respect to its design, analysis, interpretation or preparation of the manuscript.

Dr. Rodu has no financial or other personal relationship with regard to the grantors. Dr. Phillips has provided consulting services to USSTC in the context of product liability litigation.

Authors' contributions
Both authors made substantive contributions to all aspects of this study, and both approve the final manuscript.

References
Debunking the claim that abstinence is usually healthier for smokers than switching to a low-risk alternative, and other observations about anti-tobacco-harm-reduction arguments

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Abstract

Nicotine is so desirable to many people that when they are given only the options of consuming nicotine by smoking, with its high health costs, and not consuming nicotine at all, many opt for the former. Few smokers realize that there is a third choice: non-combustion nicotine sources, such as smokeless tobacco, electronic cigarettes, or pharmaceutical nicotine, which eliminate almost all the risk while still allowing consumption of nicotine. Widespread dissemination of misleading health claims is used to prevent smokers from learning about this lifesaving option, and to discourage opinion leaders from telling smokers the truth. One common misleading claim is a risk-risk comparison that has not before been quantified. A smoker who would have eventually quit nicotine entirely, but learns the truth about low-risk alternatives, might switch to an alternative instead of quitting entirely, and thus might suffer a net increase in health risk. While this has mathematical face validity, a simple calculation of the tradeoff -- switching to lifelong low-risk nicotine use versus continuing to smoke until quitting -- shows that such net health costs are extremely unlikely and of trivial maximum magnitude. In particular, for the average smoker, smoking for just one more month before quitting causes greater health risk than switching to a low-risk nicotine source and never quitting it. Thus, discouraging a smoker, even one who would have quit entirely, from switching to a low-risk alternative is almost certainly more likely to kill him than it is to save him. Similarly, a strategy of waiting for better anti-smoking tools to be developed, rather than encouraging immediate tobacco harm reduction using current options, kills more smokers every month than it could possibly ever save.

Introduction

Tobacco harm reduction (THR), the substitution of low-risk nicotine products for cigarette smoking, is increasingly recognized as offering huge public health benefits. Smoking is well known to be a very hazardous activity, but the main reason why people smoke – nicotine – does not itself cause much risk when separated from inhaling smoke. Extensive epidemiology shows that the use of Western oral smokeless tobacco (ST) causes a trivial fraction of the mortality risk from smoking, and it is believed that electronic cigarettes and pharmaceutical nicotine products (gums, patches, lozenges) have similarly low risks. Many smokers will keep smoking until they die from it because when given only the options of smoking or completely giving up nicotine, many will not give it up. But many of them probably could be persuaded to switch to a low-risk source of nicotine, and the health benefits would be almost as good as quitting entirely.

Readers interested in background on THR that is beyond the present scope, including quantifications of its potential benefits and reports of past successes, can find them in our website [1], in various overview papers (Phillips CV, Heuver K, Bergen P. Tobacco – the greatest untapped potential for harm reduction. Submitted, Available at: http://www.tobaccoharmreduction.org/whpapers606.htm) [2,3], and in endorsements by British and American medical organizations [4,5]. Other relevant contributions to the issue include studies that allow estimates of the potential benefits (Geertsema K, Phillips CV, Heuver K. University Student Smokers’ Perceptions of Risks and Barriers to Harm Reduction, Submitted, Available at: http://tobaccoharmreduction.org/whpapers001.htm) [6,7], estimates of how much THR has already been employed in the past in the U.S. [8], and how it has largely succeeded in Sweden, where ST has substantially replaced smoking, resulting in the lowest tobacco-related disease rates in the Western world [9,10].

Stated estimates for how much less risky ST is compared to smoking vary somewhat, but the actual calculations put the reduction in the range of 99% (give or take 1%), putting the risk down in the range of everyday exposures (such as eating french fries or recreational driving), that provoke limited public health concern [6]. Even this low risk is premised on the unproven assumption that nicotine causes small but measurable cardiovascular disease risk (as do most mild stimulants such as decongestant medicines, energy drinks, and coffee), since such risks account for almost all of the remaining 1%. Perhaps just as important, even a worst-case scenario puts the risk reduction at about 95%, meaning that any scientifically plausible estimate shows THR has huge potential health benefits. There is no epidemiology for the new electronic cigarettes and very little useful epidemiology for assessing long term use of pharmaceutical nicotine products. But since most of the apparent risk from ST comes from nicotine, and the other ingredients in the non-tobacco products are believed to be quite benign, we can conclude that the risks across these product categories are functionally identical from the perspective of THR.

Because it is not necessary to distinguish among product categories for purposes of the present analysis, a collective description, THR products, is used. Product preferences vary and many smokers become attached to aspects of the smoking experience, including the aesthetics (flavor,
smell, mouth and airway feel) and social behaviors for which no other product is a perfect substitute. The variety of THR products increases the chance that a given smoker will find one of them a sufficiently good substitute for smoking.

Harm reduction is a generally accepted public health principle that recognizes that eliminating an exposure is often not practical, welfare maximizing, or ethical, and so we should endeavor to reduce the harm from the exposure. The best example is encouraging the use of seatbelts without trying to curb exposure to automotive transport. However, for politically controversial exposures (e.g., injection drug use, sexual activity outside of marriage, tobacco use) opponents of harm reduction often try to defend their beliefs that “just say no” (abstinence only) is the only acceptable option by observing that “lower risk does not mean no risk”. But in the absence of quantification, this observation is merely a trivial vocabulary lesson, not a useful contribution to decision making. The present analysis offers a quantification that illustrates how a 99% reduction in risk is no close to zero risk that the “let’s wait and see if we can do even better than current low-risk options” attitude is clearly killing more people than it could ever save. Rational decision strategies call for taking advantage of existing knowledge at some point, rather than continuing to search. If a risk is low enough, it is obviously better to accept that risk than to stick with high risk levels hoping that a way to achieve even lower risk will be discovered.

Harm reduction is particularly compelling for the use of nicotine because so many people have such a strong propensity for using it. Nicotine is a very beneficial drug for many people, providing alertness, focus, pleasure, and relief from a variety of psychological symptoms and pathologies. A substantial fraction of the population gets these benefits by smoking even though the health costs are so high, which means that demanding they quit entirely entails great welfare costs and is not likely to work.

Smoking can be described compellingly in terms of normal welfare economics, such that the consumer is maximizing his welfare by choosing the available options (smoke or not smoke). Both choices have costs and benefits, and some consumers judge that the benefits of smoking outweigh its very high costs. However, for many such smokers, the possible reduction in benefits from switching to a less-enjoyed product would be greatly outweighed by the reduction in costs from health risks, so knowing about the benefits of switching to a THR product would be tremendously beneficial. Alternatively, it is often implicitly argued that smoking behavior does not conform to rational choice theory: Smokers do not choose smoking from among their options, but rather “addiction” (a rather slippery concept which is seldom actually defined, but is still widely invoked and accepted) or some related phenomenon prevents smokers from being able to choose to be abstinent. In that case, THR offers a health benefit that is not going to be achieved by choosing abstinence, and thereby also provides a great welfare benefit. Thus, if either of these models of individual behavior leads to the same conclusion: Many people who are faced with the dichotomous choice of smoking and abstinence will not just quit, and many of them would be better off using nicotine in a low-risk form. Therefore, whether one believes that smokers are making a rational welfare-maximizing choice or are victims of a curse, THR makes sense from the perspective of both individual welfare and public health. (Further exploration of the policy-ethics arguments surrounding promotion of THR can be found in the collection of papers at http://www.tobaccoharmreduction.org/swapapers010.htm.)

It might seem surprising that something as promising as THR is largely unknown and unimplemented as a policy. Much of the problem is that people (smokers, health educators, policy makers) hear the messages that THR products are not safe, that “all tobacco is deadly”, and “the only safe choice is to quit entirely”. This convinces people that THR either is not possible at all or represents only a marginal improvement that is not worth pursuing. Still, this begs the question of why anyone would choose to deliver the message that a 99% reduction in risk is almost as bad as continuing to smoke, rather than the obviously more accurate message that it is almost as good as quitting entirely. Answering this is useful for understanding the significance of the analysis presented here.

Why analyses like this one are needed

The discourse surrounding tobacco policy and education is dominated by people who pursue the most extreme possible goal regarding tobacco: unconditional elimination of its use. Explicit statements of that goal are very common. Their goal is not to design tobacco policies that maximize human welfare or even that maximally reduce physical health costs. Any such concerns are, at best, secondary to the goal of simply reducing consumption of all forms of tobacco, and usually also reducing any long-term self-administration of nicotine that has been extracted from the tobacco (i.e., electronic cigarettes and pharmaceutical products). Thus, while getting smokers to switch to using ST represents an almost perfect success from the public health perspective (and is even more attractive from the human welfare perspective), it represents little or no progress for someone pursuing the goal of unconditionally eliminating tobacco use from the world. Presumably those who believe that eliminating tobacco is the appropriate goal would not dispute this. With this in mind, it is much easier to understand why some people reject a 99% reduction in risk as not worth pursuing: reducing risk is not the major factor in their objective function.

(This, of course, does not address the question of why anti-tobacco extremists are motivated to pursue this goal. Exploring possible explanations is beyond present scope (they are discussed in a bit more depth in Phillips, Heavner & Bergen (Phillips CV, Heavner K, Bergen P. Tobacco – the greatest untapped potential for harm reduction. Submitted. Available at http://www.tobaccoharmreduction.org/swapapers006.htm)). The list includes: the economically absurd belief that nicotine products provide no benefits and thus no one really wants to use them, usually closely tied to the paternalistic notion that the activists are better able to determine what people really want than the consumers themselves; an irrational hatred of companies who make nicotine products (often with the exception of pharmaceutical companies who many anti-smoke activists are closely allied with); the common drug war mentality of wanting to purify everyone and considering users to be sinners; and simple involvement of individual ego, whereby the goals becomes about winning the race and defeating the opponent, without ever admitting that their strategy may not have been optimal, rather than trying to develop humane, rational, practical policies.)

Understanding this is critical because those pursuing the extreme anti-tobacco agenda are often
thought to have risk reduction as their primary objective, and take advantage of this by making dozens of health risk claims. It is, of course, people’s right to hold the political opinion that we should work toward eliminating all tobacco use, regardless of how pursuing that goal would affect people’s welfare and health, and it is those advocates’ right to campaign for their goal. The ethical problems and public confusion result when the primary goal is eliminating tobacco, but the rhetoric mostly consists of claims about health. When such a disconnect occurs, the claims are merely rationalizations or attempts to persuade those who might not be persuaded by the true goal, rather than representing true underlying motives. When the language of science is used to rationalize rather than analyze, the probability is high that the science will degenerate into pseudo-scientific rhetoric.

None of this should come as a great surprise given the history of other abstinence-only agendas presented in the guise of public health. It has long been accepted by the public health community that harm reduction strategies for illicit drug use, from needle exchanges to education about the advantages of moderation, save many lives. Nevertheless, anti-drug warriors who support a “just say no”-only strategy frequently try to shut down programs that promote harm reduction. Their explicit argument is never “those criminals deserve to die if they do not quit using drugs, so we should not try to lower their risk”; in fact, their public argument is often based on inaccurate claims that the harm reduction strategies increase risk. Similarly, it has been known for decades that abstinence-only approaches to sex education in the West produce inferior health outcomes compared to balanced harm-reduction-oriented education, combined with product and service provision. Activists who persist in claiming that promoting only sexual abstinence is health-improving seem to not be concerned with health so much as they are just annoyed that people are enjoying sex outside of marriage.

The politics and rhetoric of the abstinence-only approach to nicotine use have much in common with these abstinence-only approaches, but this is not yet widely recognized. As a result, many people who are genuinely motivated by promoting personal and public health, and do not share the extreme anti-tobacco agenda, often believe the inaccurate health claims that are really rationalizations for the anti-tobacco position. Since this often is to the detriment of both public health and the scientific legitimacy of the health sciences, it is important for the public health and scientific communities to debunk these claims.

Debunking these claims is a difficult challenge. Anti-THR health claims are typically speculation or assertion, without the support of evidence or analysis, and thus actual scientists will immediately relegated them to the realm of, at best, speculative hypothesis. But it is easy to take advantage of laypeople’s tendencies to accept at face value all manner of urban myths and other misconceptions, and to demand scientific proof that the claim is wrong [11]. Endeavoring to disprove a long list of assertions is far more difficult than making up those claims in the first place. Indeed, the sheer number and ever-changing nature of those claims is further evidence of attempts to rationalize a pre-determined conclusion, not an exploration of real reasons:

Methods of responding to misleading claims

But though trying to dispel unsubstantiated claims is not considered necessary in scientific thinking and is obviously an epistemic nightmare, it is necessary to advance public health policy. Advocates of THR have endeavored to debunk some of the most erroneous anti-THR claims. Some claims have been debunked by simply pointing to existing scientific literature (e.g., claims that ST use causes substantial disease risk are contradicted by decades of epidemiologic evidence to the contrary). Some claims have required new directed empirical work (e.g., the claim that promoting THR would create a “gateway” to smoking required focused empirical research and analysis to debunk). Still others are hypothetical scenarios that require an analytic approach to show they are misleading or of minor consequence.

An example of such analysis is the debunking of the claim that if we allow smokers to learn that they have low-risk alternative sources of nicotine, then many people who might have had zero risk from consuming nicotine (because they would have quit entirely or not started) will choose to consume ST or pharmaceutical nicotine and suffer some small risk. This will, the claim goes, increase total population risk. But when it is demonstrated that net social risk could not conceivably increase in this manner, anti-THR activists sometimes counter with a second assertion: Even though total population risk will decrease, there are many smokers who would have quit nicotine entirely but instead switch to a low-risk product and they will suffer greater risks than they otherwise would, and that this constitutes an argument against THR. Debunking this requires the additional analysis presented below.

One might argue that the ethical considerations make quantifying this claim irrelevant. The leading deontological tenet of modern health ethics is the obligation to provide people with accurate information so that they can make informed autonomous decisions about their own health. Thus, whatever one might think about actively promoting THR as public policy, it is per se unethical to mislead people in order to manipulate their health behavior, even if it is “for their own good” (Phillips CV. The affirmative ethical arguments for promoting a policy of tobacco harm reduction. Submitted, Available at: http://www.tobaccoharmreduction.org/wpapers/010.htm). In other words, preventing a smoker from learning about a low-risk alternative, even if he is about to quit entirely, is clearly unethical. Moreover, a consequentialist analysis reveals that someone who chooses to forgo nicotine because of the high cost of smoking but, upon learning of a low-risk way to consume nicotine, chooses to consume low-risk nicotine must have concluded that the net welfare benefits of consumption (the benefits of nicotine, net of the health and other costs) are positive, even though the net benefits of smoking were negative. Therefore misleading people about the option necessarily has net negative welfare impact (Phillips CV. The affirmative ethical arguments for promoting a policy of tobacco harm reduction. Submitted, Available at: http://www.tobaccoharmreduction.org/wpapers/010.htm).

Nevertheless, some observers are unconcerned with these ethical arguments. More importantly, the claim brings up an interesting analytic question that is worth answering even apart from the politics of THR. In terms of physical health risks, someone who keeps smoking is clearly worse
off than someone who switches immediately, who in turn is probably slightly worse off than someone who immediately quits entirely. But how long would someone have to keep smoking before his health risks would have been lower had he just switched today and used low-risk nicotine for the rest of his life? Or, equivalently, how much time can pass while powerful interests vilify THR products while waiting for theoretical perfect alternatives to emerge before that delay kills as many people as using THR products ever could? For anyone who is primarily concerned about maximizing health outcomes (even apart from right to autonomy or welfare maximization), the answer to these questions should make it clear that THR should immediately be embraced using currently available alternative products.

Analysis

It is illustrative to begin this analysis by addressing the assertion that total social (population) risk will increase if THR is embraced, explaining how that is insupportable, before continuing to the new analysis of the individual smoker who will either switch or quit.

Net effect on social risk of lowering individual risk

It is clear that lowering the risk from consuming nicotine (or, more precisely, making people aware of the fact that they have the option of lowering their own risk) should result in some people using nicotine who otherwise would not. Simple economics tells us that when the population learns that they can receive the benefits of nicotine with much lower total cost (due to almost eliminating the health risk), rational behavior causes increased consumption. This means that demands like the Society for Research on Nicotine and Tobacco's (SRNT) policy statement, "[THR] should not reduce the likelihood of eventual cessation of tobacco use" and "should not lead to increased population prevalence of tobacco use" [12] are tantamount to saying that any step that lowers the risk from using tobacco -- whether it be creating a safer product or finding a cure for lung cancer -- is unacceptable. This is critical to understand: Finding a cure for lung cancer would inevitably increase the number of people who smoke, and thus the SRNT is demanding that no such cure be pursued. More generally, insisting that a health policy or technology, even one that saves many lives, is only acceptable if it does not lead to an increase in the number of people engaging in risky activities would not only forbid THR, but would also prohibit condoms, sports safety equipment, sunscreen, lifeguards, vaccines for travelers, and trauma centers.

In fairness, those who make such statements are probably not intentionally calling for a prohibition against lowering the risks from smoking, such as by demanding that we avoid curing cancer. They are probably just ignorant of basic economics and how changing costs influence people's decisions. Though there are skilled economists involved in "tobacco control" research and advocacy, they seem to have done little to educate or influence activism or policy statements. The most vocal activists are clearly unaware of the overwhelming economic evidence about how individuals optimize consumption, or reject that evidence without any basis for doing so, and thereby reject the liberal ethics of economics-based consumer policy that follow from it. This is not merely a matter of considering individual smokers as irrational, since it even extends to assuming profit maximizing businesses do not follow their best interests -- e.g., they insist that prohibiting a popular voluntary commercial choice, banning smoking areas in parks, does not merely result in a net health improvement, but actually never hurts any merchant [13]. However, even though economic ignorance is a compelling explanation, we cannot rule out the possibility that many anti-tobacco extremists really mean what they say, and actually favor maximizing the risk from using nicotine and otherwise intentionally lowering people's welfare in order to make tobacco/nicotine use less appealing.

Empirical support for the economic prediction that lowering risk will increase consumption (either by more people consuming the good, or those who are consuming it using more, or both) can be found in Sweden. Most Swedish would-be-smokers (particularly men, but increasingly
women also) use ST instead, resulting in by far the lowest consumption of smoked tobacco in the Western world. The result is the expected reduction in smoking-caused diseases, with the offsetting increase in ST-caused diseases (which is to be expected, since no detectable level of any disease has been shown to be caused by ST). But total tobacco consumption in Sweden is among the highest in Europe. Anti-tobacco extremists, therefore, consider the Swedish experience to represent a failure, consistent with their political goal of reducing tobacco use regardless of the health effects. Realizing, however, that most observers would not share that goal, they try to rationalize their position that this public health triumph is really a failure by trying to deny the public health gains.

Indeed, it should be recognized as a reassuring observation about people to see that when the health risk from a consumption choice is dramatically reduced, people rationally increase total consumption. Many readers will probably find it odd to declare it reassuring that more people would become nicotine users, but a single observation should be sufficient to eliminate all confusion: The prediction that some people would not smoke will choose to use low-risk nicotine products is equivalent to the more politically correct statement, "some people choose to avoid smoking due to the high health costs even though they would like to get the nicotine." Few would disagree that the latter is a reassuring observation about people's rationality.

Extending this, it is plausible that lowering the health risks of consuming something could increase consumption to the point that the total social risk will increase. It must be the case that there is an improvement in total net social benefits, since the change would result from free choice of a preferred option, and the major externality would likely also be positive. But health risk, considered apart from other contributors to welfare, might increase. All that is necessary for an increase in health risk is that the quantity consumed goes up by enough that even with the lower risk, the total risk (i.e., quantity consumed multiplied by average individual risk per unit of consumption or, in units of people, the number of consumers multiplied by the average risk per consumer) is greater. Whether this happens in a given case is an empirical point, but for the case of smokers and some nonsmokers adopting a low-risk nicotine product, a simple analytic reality check shows that it is effectively impossible.

Given the estimate that switching to a low-risk alternative reduces a smoker's risk by 99%, if only 1% of a population switched from being continuing smokers to using THR products, then even if the entire rest of the population switched from no consumption to the low-risk products it would not result in a social risk increase. (The number of additional users necessary to make up for the risk decrease from one smoker is easily calculated as \((1-x)/x\), where \(x\) = the proportion of the risk from smoking caused by the THR product, so since \((1-0.01)/0.01=99\), then for 1 smoker who switched from smoking, there would have to be 99 non-smokers who took up ST to make up for it.) Even if the alternative product was 5% as harmful as continuing to smoke, which is difficult to imagine given the available evidence, if 1% of the population switched (which would represent less than 5% of all smokers in Western populations, a very modest success), the new product would have to attract 19% of the population, roughly one-quarter of all current non-smokers, to start using nicotine in the low-risk form to result in no net gain. This would represent total nicotine usage prevalence close to the maximum it ever reaches, even in populations not worried about health risks, which is presumably the total portion of the population that benefits from using nicotine. Thus, even a pessimistic comparative risk scenario leaves little room for an increase in social health risk.

The argument that total population risk might increase and therefore we should not inform people about THR — though arithmetically absurd and based on the unethical premise that it is acceptable to mislead people — has proven to be a remarkably persistent rationalization for anti-THR activists. It is so often repeated that the original debunking of it, an article that basically just graphs the \(y = (1-x)/x\) function and expands on the point from the previous paragraph [14], has been cited by scores of journal articles about THR (including most of the substantive overview articles on the topic) and hundreds of presentations and popular communications, presumably because the later authors believed it was necessary to respond to the claim that the article debunked. But there has not previously been a good quantitative response to the next layer of rationalization: Even though social risk will clearly be lower if THR is widely adopted, somewhere out there is a hapless smoker who would have soon won his struggle to give up nicotine to avoid all further health cost, but he becomes doomed to failure when presented with the information that he could use a low-risk alternative, resulting in a net health cost.

This claim, plausible until one actually checks the numbers, typically takes a form like THR "may undermine efforts leading to the healthiest outcome of all, namely, complete tobacco abstinence". Versions of this claim are common in statements made to the popular press by anti-THR activists and in rhetorical documents put out by anti-tobacco extremist organizations (though this particular quotation actually comes from an ostensibly scientific journal article [12]). Setting aside the inappropriate breadth of this phrasing (it is generally accepted that "healthiest" should incorporate psychological health, not just longevity, and since nicotine has substantial psychological benefits, abstinence is often not healthiest), the implicit claim is quantitative and a function of the time periods involved. Claiming that the outcome the authors personally prefer, abstinence, is healthiest (in the narrow sense of maximizing life expectancy) depends on the implicit quantitative claim that the hypothetical complete cessation of nicotine use would have begun soon enough that it would have resulted in less physical health risk than consuming a low-risk alternative. (Some might claim that such authors are merely suggesting that immediate abstinence would be the physically healthiest behavior, without reference to what might actually happen. But this defense is not convincing since the statements are made in the context of policy recommendations and other practical discussions, where obviously no one would suggest that assessing the effect of universal immediate abstinence has any practical relevance. After all, if the authors merely wanted to make a statement about what would be best, without regard to what is actually possible, then making it so that no one ever smoked in the first place would actually be best.)

Sometimes the claim is made in a form that practically concedes that eliminating tobacco use (and often any close substitute for it, like electronic cigarettes), rather than improving health, is the author's primary goal (e.g., "The major concerns of promoting a dangerous product as less harmful than another are that it may undermine efforts to achieve total tobacco-product cessation" [15]). However, such claims are typically presented in a way to imply that readers
concerned with health outcomes should consider them to be health-based (in the previous example, the assertion appeared under the heading "public health implications of the findings from this study"). But even authors editorializing a pro-THR position, and thus presumably not basing their views on the anti-tobacco extremist position, often suggest that a "downside" [16] of having the option to switch will cause some people who would have quit entirely to suffer greater risk because they switch instead. But how many potential quitters actually fall into this "downside"? That is, how many were going to quit soon enough that switching actually represents a net increase in disease risk?

Calculation of the switch-versus-eventually-quit tradeoff
The following analysis quantifies the question about "soon enough". Note that this calculation addresses only the risk-risk tradeoff, ignoring any benefits of continuing to use nicotine rather than quitting and the welfare costs of the act of quitting. It is also limited to mortality even though non-fatal morbidity is probably not perfectly proportional to mortality risk. The latter simplification, as well as the necessarily rough input numbers, are relatively minor compared to the simplifications that exist (though are seldom acknowledged) in most population health analyses. More important, they prove to matter little, given the clear implications of the result. This analysis proves to be an excellent example of the value of a back-of-the-envelope calculation as an adequate response to an unanalyzed claim: While it is often not practical to complete a precise analysis of a scientific or policy claim, it is often the case that the rough analysis that is practical is quite adequate for present needs, and is a great improvement over unquantified speculation.

For any given smoker at a particular time, who is not already doomed to die from his smoking to date, we wish to estimate how many days of continuing smoking causes as much risk of death as a future lifetime of using a low risk nicotine product. (Note: describing something as causing someone's death is shorthand for saying that it substantially hastened the death, and obviously not that ever-dying was conditional on the behaviour.)

Answering the question for an individual would require determining the probability of dying from a lifetime of THR product use, starting at the present, and the probability of getting from future smoking as a function of how long the smoking continues. While it would be useful to have such a lifecycle-based model for individual decisions, it is not currently possible. An individual's risk from a lifetime of THR product use could be reasonably estimated as a function of the individual's current life expectancy, with possible refinement by inclusion of other variables. But despite the extensive research on smoking and health, there is apparently no good calculation of the risk from a short future period of smoking, based on current age, sex, etc. There is ample research about the benefits of quitting and it clearly establishes that quitting sooner is better, but it offers very limited information for calculating the marginal cost of a given additional period of smoking as a function of past smoking duration and other individual characteristics. Thus, while comparative observations are possible based on the demographics of the individual in question (e.g., a very young smoker, with a long potential period of THR product use, has more to lose from switching rather than quitting after a particular delay, and thus could afford a longer wait until quitting), there is currently no realistic way to do this calculation for individuals.

But from the public health education and policy perspective, knowing the risk-risk tradeoff on a population average basis is almost as useful, and calculating that is possible. The population average can be viewed as comparing switching-now-versus-quitting-later for all smokers acting simultaneously (which, of course, will not happen – it is just a useful unit of analysis) or, equivalently, asking the question for a random smoker we know nothing about. Public health interventions, particularly the provision of information, typically affect all or random individuals, making this the relevant level of analysis.

The key to the calculation is the observation that if we assume that smoking more never cures a disease that was caused by previous smoking, then for anyone who dies from smoking, there will be a day, D, in his smoking history such that if he had quit entirely before that day, he would not have died from smoking, but as a result of smoking through that day, he does die from smoking. Because we never know which day that is, and because smoking-caused disease results from an accumulation of insults, this observation may not be obvious to all readers. For those who do not find this observation intuitive, a simple proof follows.

Proof: Assume that a destined-to-be-fatal disease that was caused by past smoking is never cured or delayed by future smoking. Consider someone who dies from smoking. Consider the latest day, if it exists, of smoking during his life such that had he quit entirely before that day he would not have died from smoking. Since this is the latest such day and he did die from smoking, if he smoked that day he would still have died from smoking, which defines day D. The smoker's life was finite, and thus includes a finite t days of smoking. Had he quit just before day t, either he would have still died from smoking (either from the disease that actually killed him or another disease also caused by smoking) or not. If not then day t meets the definition of D (if he had quit the day before he would not have died, and it is necessarily the latest such day). If day t is not D, then either he would have still died from smoking if he had not smoked on day t-1, in which case day t-1 is D (if he had quit before that day he would not have died, and this is not true for any later day). If t-1 is not D then a similar analysis can be applied to t-2, and so on. Thus, by counting down through the finite list of days, we either find some day that is D or reach day 1 without having found D, in which case quitting any time after day 1 would not have stopped the death from smoking. By hypothesis the death was caused by smoking, so never starting (quitting before day 1) would have prevented it, and therefore day 1 is D. Therefore, D exists sometime within the days of smoking for each individual who died (or is destined to die) from smoking.

The same logic proves that for every smoker who dies of smoking there was one particular cigarette that was the fatal point-of-no-return. The proof does not address the fact that moving toward quitting might alter which day is D by altering smoking intensity or starting and stopping. It also ignores the possibility that further smoking past D could further accelerate the death from smoking, making the subsequent analysis conservative because it ignores the possible longevity benefits of switching among those already doomed to die from their smoking.
Given that everyone who dies from smoking has a D, it is possible to estimate the increased risk of dying from smoking for the average smoker (or all smokers) from smoking one more day. For a typical Western population, we can estimate the average lifetime days of smoking for someone who dies from smoking to be about 18,000 (about 50 years). Since one of those days must be D, the average day of smoking from someone who is destined to die from smoking (averaged across all days of smoking among all such individuals) has probability 1/18,000 of being the day that doomed the smoker to die from smoking. Thus, if all current smokers who are destined to die from smoking gave up smoking tomorrow, some number, x, of them would be saved from dying from smoking, but if instead they gave up smoking tomorrow night, only x minus 1/18,000th of that population would be saved.

Notice one immediate observation based on this that is apparently not obvious to many smokers and people who give advice on these matters: Quitting someday is not sufficient — it is possible to quit too late and there is no way to know in advance which day is one day too late.

Estimates for Western populations of the fraction of current smokers whose deaths will be caused by smoking range from 1/4 to 1/2, so roughly one death from smoking is caused by each 50,000 days of smoking. The best available estimate is that the average risk of dying from THR product use is about 1% that from smoking. Following the above logic, this represents 5x10^6 days of use per death caused. Since the ratio of the risk from THR product use compared to smoking enters the calculation linearly, readers who believe the ratio is really 2% or 3% can adjust the final estimates upward by a factor of 2 or 3. (Readers who believe the ratio is much more than that should take a closer look at the scientific evidence.) Assume that the total risk from THR product use is the same whether it is a lifetime of exclusive THR product use or switching to THR products after some period of smoking. Note that this is a conservative assumption, since any smoker who is already doomed to die from smoking experiences no increase in the chance of dying from nicotine by using a THR product. Moreover, it seems likely that all THR product use causes any negative health impacts other than the minor effects of nicotine itself, then they are not exactly the same as those from smoking, and so the additive health effect of THR product use on top of smoking would probably be less than the additive effect of a longer term of THR product use.

We can estimate that if smokers who are going to eventually cause themselves to die from smoking will smoke an average of 18,000 days, then the average such current smoker has about 9,000 days of smoking ahead of him. (This is would be exactly true if we were in steady-state with respect to smoking and if smokers with fewer days of smoking ahead of them were not more likely to already be deceased. Failures of these assumptions will tend toward canceling out, and the net error seems to be within the limited precision built into the calculation.) Thus, using the conservative simplification above, if the average smoker switches immediately, he has a 9,000/5x10^6 = 1/600 chance of dying from ST use. Comparing this to his extra probability of dying from smoking by waiting longer to completely quit, at 1/18,000 chance of dying per day, shows that this is the equivalent of delaying quitting by about one month. Thus, on average, a smoker only endures greater total risk from using a THR product for the rest of his life if he were going to become abstinent in less than a month.

Note that the “all smokers” or “randomly selected individual” condition is crucial here since, for example, a particular smoker who is young and therefore has not yet smoked much can probably get away with smoking years more before being doomed, but has many more days of potential THR product use ahead of him, might not reach risk parity for several months. Conversely, there are older demographic groups, possibly identifiable, who may not yet be doomed but are much more likely than average to be close, for whom a single additional day of smoking poses greater risk than a future lifetime of THR product use.

Discussion

While it is logically possible that lowering the risk from an exposure could increase population risk, the (1-x)/x calculation shows this is not plausible for THR. The suggestion that, despite the lower population risk, many individuals might still face greater risk is also logically possible, but the calculation presented here shows that this is not a substantial practical worry.

On average, a smoker who is going to take more than a month to quit entirely (or will experience relapses that will have a similar health impact — probably roughly a total of one month worth of days) will have less total health risk by switching immediately, even if he never quits the alternative product. The typical pattern of even dedicated quitters, starting and stopping smoking for a year or two, will cause much more risk than switching to a low-risk alternative. Moreover, even an average smoker who was going to successfully quit after only a week or two more will suffer only a tiny net increase in physical health risk from switching now, a change so trivial compared to the net benefits of switching for smokers who will not quit for years or ever that it is clearly inconsequential.

The practical implications of this analysis do not change based on plausible variations in the input parameters, including the risk from using ST. Even if we use a completely implausible high risk from ST use, say that it causes 10% of the risk of smoking, then if an average smoker would have taken ten months to quit entirely, he would have had lower risk had he switched immediately. The break-even might be as low as about a half a year — recall the conservative assumption built into the calculation. Thus, even discovering that ST use is an order of magnitude worse than the simple current evidence suggests would not fundamentally change the implications of the analysis.

Since this analysis is based entirely on mortality risk, it ignores other contributions to welfare. The reason that current smokers have not already quit, in spite of the health benefits of doing so, is that it would have resulted in substantial costs to them and, similarly, whenever a smoker chooses to switch it implies that there is a net welfare benefit (compared to either smoking or abstinence) to using the alternative product. This welfare gain from switching rather than quitting probably dwarfs the welfare implications of the mortality risk from low-risk products, though quantifying that is beyond the present scope.

Finally, it is worth noting that someone who switches from smoking to a low-risk alternative still
has the option of quitting entirely, lowering his risk slightly more still. Indeed, there is reason to believe that eventually quitting alternative products is easier. This means that even the young smokers who might have been better off with several more months of smoking rather than a lifetime of THR product use stand a good chance of quitting entirely anyway (if they decide that the benefits of consumption are outweighed by the benefits of quitting), further favoring the option of switching now. Even those smokers who cannot afford another day of smoking but fortunately switch just in time (who are likely from older demographics that are the primary target for THR) could then survive long enough to quit nicotine entirely.

Many of the claims about health risk made to try to discourage the adoption of THR have been proven to be out-and-out false. This includes the "total social health risk will increase" claim. The present analysis does not relegate the "some people would be stopped from quitting entirely and thus have worse health outcomes" claim to universal falsehood—it will still inevitably be true for a very few individuals. But this is common in public health interventions, from automobile safety equipment to vaccines—the net social effects are overwhelmingly beneficial, though some people (who cannot be identified ex ante, and often not even ex post) suffer net harm rather than benefit. The analysis shows that only a tiny portion of all future quitters will be quitting soon enough that they would have higher expected risk by switching immediately. Moreover, the net increase in expected risk even for those individuals would be extremely small, and the net welfare effects would still be positive. Clearly, then, the claim does not represent a sufficient concern to override the huge net expected social benefit, to say nothing of the ethical requirement that smokers be informed about their options. The claim is thus relegated to being a distraction from rational and honest discourse on the subject, not a contribution to it.

This calculation emphasizes the cost of delaying the adoption of THR at the individual level also. Those of us who promote THR are familiar with smokers who, upon learning about THR, insist that they do not need to consider that option because they will eventually be exercising the "perfect" option of quitting anyway. But many such individuals never quit, and almost none quit in time for it to be a healthier choice. Similarly, each additional month that anti-THR activism keeps a potential quitter from learning about THR is more likely to kill him than is a lifetime of using ST or another low-risk nicotine product. To put it bluntly, anti-THR activism and disinformation do far more damage to public health than smokeless tobacco, electronic cigarettes, or other THR products ever could.

Since THR can be self-tailored and requires no clinical or government intervention, it does not matter that there may be smokers for whom no low risk product is an adequate substitute or that there is no political will to actively endorse it. THR can be adopted by individuals who do find an acceptable substitute, and likely will be widely adopted if smokers were simply given accurate information. The usual explanation for the lack of such information is that anti-tobacco extremists promulgate disinformation and then even the opinion leaders who are genuinely concerned about public health repeat the inaccurate claims because they have been misled. But another explanation is misplaced optimism on the part of the public health leaders: That is, many may not be misled by the disinformation about THR, but may genuinely believe that most smokers will successfully quit using nicotine very soon or that a perfect new anti-smoking method, policy, or product will be developed and cause everyone to quit soon, reducing their risks more than THR would. The present analysis shows just how overly-optimistic that belief needs to be in order to justify the failure to immediately promote THR using current technology.

Whatever the explanation for it, the present analysis shows that anti-THR activism is deadly. Hiding THR from smokers, waiting for them to decide to quit entirely or waiting for a new anti-smoking magic bullet, causes the deaths of more smokers every month than a lifetime using low-risk nicotine products ever could.

Competing interests
The author is an advocate of tobacco harm reduction, and thus has worldly goals that are furthered by debunking anti-THR rationalizations. He is also interested in improving research in public health and promoting evidence-based public policy, and thus has an interest in calling attention to flawed reasoning. In particular, he has long taught his students the value of back-of-the-envelope analysis and related reasoning, and so is motivated to seek examples that demonstrate its usefulness. The author has been the target of a well-documented campaign of attacks by anti-THR activists trying to damage his career and force him to stop doing THR research [17]. While nothing in this paper is a specific response to those attacks (the worst attacks have come mostly from minor local activists and the administration of the University of Alberta School of Public Health, not the internationally-known political activists cited in this paper), anyone who takes the concept of competing interests seriously will realize that such personal experiences may motivate behavior in ways an individual is not consciously aware of.

The author's research is partially supported by an unrestricted (completely hands-off) grant to the University of Alberta School of Public Health from U.S. Smokeless Tobacco Company; the funder has had no input into the design or content of this analysis, and were not aware of it until it was made available to the public. For more importantly, this author, like almost all other health researchers, is dependent on getting future funding from someone, future positive peer reviews, etc., if he is to continue his research, which in this case creates the conflicting incentive to push the frontiers in supporting the wisdom of THR (to make the research agenda more accepted) and for minimizing confrontations with powerful interest groups (to make himself more acceptable). The author advises many organizations on tobacco harm reduction, some of which are companies that profit from selling nicotine products, and is sometimes compensated for his time. In addition, he consults for USSTC in the context of litigation, has minor financial interests in the financial health of certain nicotine product manufacturers, occasionally uses several of the products mentioned in this paper, and has friends who have no intention of ever quitting their use of nicotine.

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Promoting Snus Will Save Lives in the USA

Zhu et al., when comparing tobacco-related behaviors in the U.S. and Sweden concluded that “promoting smokeless tobacco for harm reduction in countries with ongoing tobacco control programs may not result in any positive population effect on smoking cessation.” [1]

We believe that this conclusion is too pessimistic.

Promotion of snus in the U.S., as a low-risk alternative for smokers unable or unwilling to quit has great potential to substantially reduce tobacco-related illness and death. Snus and selected other smokeless nicotine delivery products can eliminate all risks from fire, second hand smoke, all pulmonary disease, most cardiac disease and most cancer attributable to smoking. These products are up to 1000 times less hazardous than cigarettes.[2,3] Thus, if large numbers of smokers replace some or all of their cigarettes with low-risk alternatives, a substantial reduction in tobacco-related illnesses and death will occur. This will be true even if large numbers of non-smokers initiate use of these smokeless products.

Zhu et al. concede that “…in the U.S., smokeless tobacco has not been promoted as a safer alternative to cigarettes.” But the American environment is even worse: current federal tobacco policy incorrectly labels a smokeless tobacco product as “not a safe substitute for cigarettes,” which has left most Americans – even healthcare professionals – with the misimpression that smokeless products are as hazardous as cigarettes.[4,5]

The popularity of “light” and “low tar” cigarettes in the U.S. has clearly demonstrated that large numbers of American smokers will switch to products that appear to be of lower risk, if encouraged to do so. While the implied health claims for “light” and “low tar” cigarettes were fraudulent, the well established differences in risk between cigarettes and smokeless tobacco products are not.[6]

One of the more intriguing findings in the Zhu paper is that “men quit smokeless tobacco products at three times the rate of quitting cigarettes (38.8% vs. 11.6%, p<0.001).”[1] This raises the possibility that encouraging American smokers to switch to smokeless products will increase the number that eventually quit all use of tobacco and nicotine.

Many opposed to such an approach claim that “conventional nicotine-replacement therapies…have been tested extensively and shown…to be effective.”[7] Such statements, however, rarely show the quit rates. One recently published study boasts that nicotine gum more than doubles the quit rate. The data show 6-month quit rates of 2.1% in controls and 5.9% in study subjects.[8] The authors fail to mention that the therapy failed for 94% of study subjects. We need to do much better than that if we are to achieve substantial reductions in tobacco-related illness and death.

Zhu et al. acknowledge – then gloss over – the fact that the rate of tobacco-related illness and death are far lower in Sweden, where snus is popular, than in the U.S., where cigarettes are dominant. Data from the World Health Organization and the International Agency for Research on Cancer show that lung cancer rates among both Swedish men and women were well under half the rates for their American counterparts from 1980 to 2002.[9] But the data reveal another amazing fact: since 1989 lung cancer among Swedish men has been lower than that among American women. This is evidence that snus use suppresses smoking, with the important context that per capita nicotine consumption is nearly identical in both countries.[10] Furthermore, the Swedish government neither promotes snus for harm reduction nor vilifies it as “not a safe substitute for cigarettes.”

The time has come for American legislators and public health leaders to educate smokers as to the differences in risk profiles between cigarettes and other tobacco products. This will empower smokers
who are unable or unwilling to quit to reduce their risk of tobacco-related illness, even while locked into their nicotine addiction. The potential public health benefit is substantial.

Those opposed to such an approach theorize that smokeless tobacco manufacturers “will inevitably target susceptible adolescents,”[7] creating users who may then transition to cigarettes. They also point out that there is no empirical evidence that such a policy (helpful information to smokers) will generate the projected public health benefits. Whether or not such a program results in increases in teen tobacco use will depend entirely on how it is framed and how it is placed in the context of other tobacco control efforts. As to the projected public health benefits, there will be no way to know for sure without implementing the policy, then carefully tracking the results. A national program in the U.S. that includes helpful health education, effective regulation, and robust surveillance and research programs should be able to make the mid-course corrections needed to assure optimal outcomes from a public health perspective.

A piece of legislation was introduced into the recently concluded 110th U.S. Congress. The bill (HR1108/S625) was known as the “Family Smoking Prevention and Tobacco Control Act.” Unfortunately, this bill, as seen by the American Association of Public Health Physicians, is a total failure with regard to the desired health education. It also fails to effectively regulate tobacco products and strongly favors currently marketed cigarettes. We hope it will be possible to amend the bill in the current Congress so that it will provide the needed health education, effective regulation, surveillance and research.[11]

The relative safety of snus and the latest generation of alternative smokeless nicotine delivery products is not a children’s issue. The eight million Americans who will die from smoking-related illnesses in the next twenty years are now 35 years of age and older. Preventing youth access to tobacco is vitally important, but should not be used as an excuse to condemn smoking parents and grandparents to premature death, especially within socially and economically disadvantaged sub-populations. If implemented as an addition to otherwise effective tobacco control programming, the helpful information to smokers should not significantly increase the numbers of teens initiating tobacco use.[11]

Conflict of Interest

Dr. Nitzkin has never sought nor secured any financial or other support from any tobacco-related enterprise. Dr. Rodu is supported by unrestricted grants from smokeless tobacco manufacturers (US Smokeless Tobacco Company and Swedish Match AB) to the University of Louisville. The terms of the grants assure that the sponsors are unaware of this work, and thus had no scientific input or other influence with respect to its design, analysis, interpretation or preparation of the manuscript.

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